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(71)(72) Applicant and Inventor: MOHLER, Sailor [US/US]; 5410 Lightening View, Columbia, MD 21045 (US).

(74) Agent: ROBERTS, Jon, L.; Roberts & Brownell, L.L.C., Suite 212, 8381 Old Courthouse Road, Vienna, VA 22182 (US).

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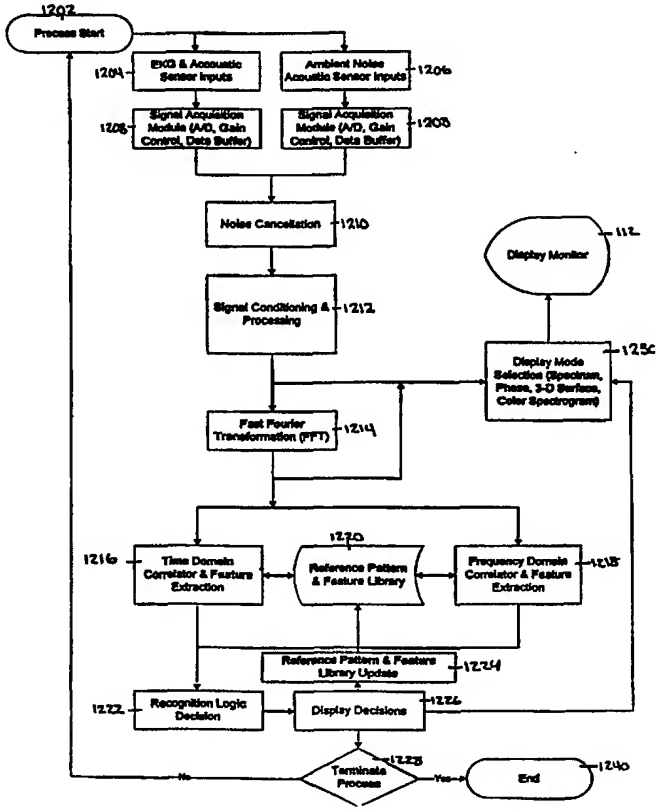
(54) Title: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT

(57) Abstract

An apparatus detection of the second heart sound acoustic signature associated with heart valve closure includes a sensor assembly (102) comprising a housing (302; 402), an electronic module (314; 422), a shock dampener (316; 432; 434), a mounting means, a transducer (320; 432; 434), an acoustic coupling (322; 436; 438) and a back cover. The sensor assembly (102) is connected to a data acquisition module (103) which in turn is connected to a signal processing means (104), a remote connection means (110) and a monitor (112). An improved acoustic coupling (322; 436; 438) is disclosed that provides low–loss acoustic transmission between the skin of the patient and the sensor assembly (102).



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TITLE: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT

FIELD OF THE INVENTION

This invention relates generally to an apparatus, operation and method for measurement of blood pressure. In particular, this invention relates to an apparatus, operation and method for the detection, identification and characterization of sounds relating to either systemic or pulmonary blood pressure through the use of sonospectrography.

BACKGROUND OF THE INVENTION

Blood pressure is the force exerted by the blood against the inner walls of blood vessels. Blood pressure determination is an important diagnostic tool. The blood vessels that comprise the vascular system can be grouped into two main divisions, a systemic circuit and a pulmonary circuit. In the systemic circuit, high blood pressure may indicate the presence of arteriosclerosis or other vascular disease, while low blood pressure may indicate shock or blood loss. Detection and measurement of elevated pulmonary blood pressure is a key diagnostic indicator for a number of pulmonary diseases, such as: cystic fibrosis, pleuresy, lung pulmonary diseases, and pulmonary impedance. Early diagnosis of these diseases greatly assists in symptom mitigation and improved patient quality of life.

The systemic circuit includes the aorta and its branches that deliver oxygenated blood to all body tissues, as well as the companion system of veins returning blood to the right atrium. Freshly oxygenated blood received by the left atrium is forced into the systemic circuit by the contraction of the left ventricle. When the left ventricle contracts, the mitral valve closes, and the only exit is through the aortic valve into the aorta.

The peripheral nature of certain systemic circuit arteries in the body extremities allows for the traditional indirect measurement of the systolic and diastolic pressures with a sphygmomanometer blood pressure cuff. While this method is effective for many patients, use of the traditional blood pressure cuff on an extremity may be contraindicated for patients suffering from any number of problems including severe extremity trauma, or burns. In patients where use of the traditional blood pressure cuff is contraindicated, there is no reliable

alternative method of monitoring blood pressure. This is extremely important in trauma patients where prompt detection of blood pressure changes are needed to counteract the effects of shock or large blood loss.

The pulmonic circuit provides for blood circulation from the right ventricle through the pulmonary valve into the pulmonary artery. The pulmonary artery extends upward and posteriorly from the heart, dividing into right and left branches which serve the right and left lungs, respectively. Within the lungs the right and left branches of the pulmonary artery divide repeatedly giving rise to arterioles that continue into the capillary networks associated with the walls of the alveoli. Gas exchange occurs as the blood moves through these capillaries, so that when the blood enters the venules of the pulmonary circuit, it is well oxygenated and poor in carbon dioxide. The pulmonary venules merge forming small veins, which in turn converge forming larger veins. Four pulmonary veins return oxygenated blood to the left atrium, thereby completing the pulmonic circuit.

None of the arteries of the pulmonic system are located in extremities and therefore measurement of pulmonic system pressure with a blood pressure cuff is not possible.

At present, the only reliable method for measuring pulmonic system blood pressure is through use of an invasive blood pressure catheter that is inserted directly into the pulmonary artery. This diagnostic procedure has a substantial degree of risk and is expensive, its use is thus generally seen as an unjustified procedure in patients without other symptoms.

The physician may attempt to detect and differentiate the abnormal sounds that occur with elevated blood pressure using traditional auscultation. Closure of the aortic and pulmonary semilunar heart valves generate a sound component that is in the audio frequency range. As the systemic or pulmonic blood pressure increases, the frequency components of the related heart valve also increase. This increased frequency audio component is not present in a healthy patient. However, aural detection of this frequency increase is extremely difficult because the physician must determine the absolute frequency of the audio component of the heart valve of interest. Additionally, the sounds are very weak and heavily contaminated with noise from other patient heart sounds, other normal patient body sounds and external ambient noise in the room. Further, the audio component of the aortic and pulmonary semilunar heart valves are heavily attenuated as they pass through the patient's chest and chest wall.

A need exists for a non-invasive, low cost and reliable means for determining systemic blood pressure in those situations where traditional means are contraindicated. A need also exists for a non-invasive, low cost and reliable means for determining pulmonary blood pressure.

DESCRIPTION OF RELATED ART

As mentioned, the sounds related to systemic and pulmonary heart pressure are difficult to discern. United States Patent No. 4,528,690 to Sedgwick; United States Patent No. 3,790,712 to Andries; and United States Patent No. 3,160,708 to Andries et al. disclose relatively simple electronic stethoscopes as methods for amplification of the sounds in an attempt to raise the sub-audible components into the audible range. However, simple amplification of the entire frequency spectrum, as disclosed, does not help in determining the absolute frequency of the heart valve sounds, or in detecting the subtle changes of this frequency that occur with changes in blood pressure.

To this end, United States Patent No. 4,594,731 to Lewkowicz and United States Patent No. 5,347,583 to Dieken et al. disclose various forms of selective filtering or signal processing on the audio signal in the electronic stethoscope. Lewkowicz discloses a means for shifting the entire detected spectrum of sounds upward while expanding the bandwidth so that they are more easily perceived by the listener. Dieken et al. discloses an electronic stethoscope having a greater volume of acoustic space and thereby improving low frequency response.

The electronic stethoscope provides a moderate improvement over conventional methods of auscultation. However, information remains in audio form only and is transient; the physician is unable to visualize the data and either freeze the display or focus on a particular element of the signal retrieved. To accommodate that deficiency, the technique of phonocardiography, which is the mechanical or electronic registration of heart sounds with graphic display, is used. United States Patent No. 5,218,969 to Bredesen et al.; United States Patent No. 5,213,108 to Bredesen et al.; United States Patent No. 5,012,815 to Bennett, Jr. et al.; United States Patent No. 4,967,760 to Bennett, Jr. et al.; United States Patent No. 4,991,581 to Andries; and United States Patent No. 4,679,570 to Lund et al. disclose

phonocardiography with signal processing and visual/audio output. United States Patent No. 5,301,679 to Taylor; and United States Patent No. 4,792,145 to Eisenberg et al. disclose phonocardiography with signal processing and visual display.

The process of phonocardiography as commonly known in the art, acquires acoustic data through an air conduction microphone strapped to a patients chest, and provides the physician with a strip chart recording of this acoustic data. The strip chart is generally created at a rate of 100 mm/second. As this method is generally used, with the exception of the created strip chart, data is not stored. Thus, it is not possible to manipulate and/or process the data post acquisition. In addition, phonocardiography does not provide the sensitivity needed to monitor softer physiological sounds such as the closure of the semilunar valves and blood flow through the circulatory system.

As previously noted, one problem in traditional auscultation is ambient noise from the room in which the examination is occurring, which reduces the signal-to-noise ratio of the sounds of interest. United States Patent No. 4,672,977 to Kroll discloses a method for automatic lung sound cancellation and provides visual and audio output. United States Patent No. 5,309,922 to Schecter et al. discloses a method for cancellation of ambient noise to enhance respiratory sounds and provides visual and audio output. United States Patent No. 5,492,129 to Greenberger discloses a method for reducing general ambient noise and provides audio output.

United States Patent No. 5,036,857 to Semmlow et al. discloses a method of phonocardiography with piezoelectric transducer. Semmlow specifically recommends against Fast Fourier Transformation analysis of the phonocardiography data and relies on processing by other means. United States Patent No. 5,109,863 to Semmlow et al.; and United States Patent No. 5,035,247 issued to Heimann also disclose piezoelectric transducers.

United States Patent No. 5,002,060 to Nedivi, discloses both heart and respiratory sensors, with Fast Fourier Transformation analysis. In the technique disclosed by Nedivi the sensors are not physically attached to the patient. Thus the sensors are not capable of detecting the low intensity sound of the aortic and pulmonary semilunar heart valves.

Devices currently known in the art do not provide either a means of determining systemic blood pressure where use of a blood pressure cuff is contraindicated, or a low risk, non-invasive means of determining pulmonic blood pressure. Additionally, the related art

does not provide the level of aural sensitivity needed to reliably detect the sounds of the aortic and pulmonary semilunar heart valves and determine the precise frequency of these sounds.

What is needed is a safe, sensitive and noninvasive means of measuring systemic and/or pulmonic blood pressure. This is accomplished through the present invention. Through the use of sonospectrography, a procedure based on integral spectral analysis techniques, systemic pressure can be monitored in conditions where traditional auscultation is contraindicated. Additionally, sonospectrography can be used to monitor pulmonic pressure in an inexpensive, noninvasive and low risk manner, allowing for the early detection of conditions such as cystic fibrosis, pleuresy, lung pulmonary diseases and pulmonary impedance. Sonospectrography is defined as the separation and arrangement of the frequency components of acoustic signals in terms of energy or time.

Further embodiments of the present invention provide a means of detecting physiological sounds, such as sounds emitted by the heart and other body organs as well as sounds related to the flow of blood through the circulatory system. Analysis of these sounds can be used to determine systemic and pulmonary blood pressure, monitor anesthesiology, determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic decrepitation, phlebitis, venous thrombosis, intravascular blood clotting and carotid artery disease.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide an apparatus, operation and method for the detection and analysis of physiological sounds, such as sounds emitted by the heart and other body organs as well as sounds related to the flow of blood through the circulatory system.

It is a further object of the present invention to provide an apparatus, operation and method to be used to determine systemic and pulmonary blood pressure, monitor anesthesiology, determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic decrepitation, phlebitis, venous thrombosis, intravascular clotting and carotid artery

disease.

It is a further object of the present invention to provide this apparatus, operation and method through the use of sonospectrography.

It is a further object of the present invention to provide this apparatus, operation and method through a synchronized and coordinated combination of sonospectrography and electrocardiogram signals.

It is a further object of the present invention to provide this apparatus, operation and method through visual display means that provide insight to the subtle characteristics of the acoustic signature.

It is a further object of the present invention to provide this apparatus, operation and method through selective time and frequency windowing of the acoustic signals.

It is a further object of the present invention to provide this apparatus, operation and method through real-time signal processing or recorded-signal post processing.

It is a further object of the present invention to provide this apparatus, operation and method through use of single or multiple transducers.

It is a further object of the present invention to provide this apparatus, operation and method through a computer assisted search algorithm to identify optimal placement of the transducer(s) on the patient's chest wall.

It is a further object of the present invention to provide this apparatus, operation and method in office environments with moderate to high ambient noise levels, through adaptive noise cancellation techniques.

It is a further object of the present invention to provide this apparatus, operation and method in a form that provides for dynamic template building to facilitate disease detection and identification.

It is a further object of the present invention to provide this apparatus, operation and method through neural network techniques.

It is a further object of the present invention to provide an acoustic coupling that minimizes signal loss between the subject-detector interface and allows for the detection of sounds heretofore undetectable in a normal room environment.

It is a further object of the present invention to extend the ability of clinicians to analyze sounds which are lower in amplitude than those detectable by the unaided ear.

It is a further object of the present invention to extend the ability of clinicians to analyze sounds which are lower in frequency than those detectable by typical auscultation techniques.

It is a further object of the present invention to increase detection of a specified frequency range through the use of a tailored bandpass amplifier.

It is a further object of the present invention to provide a means for data storage, data manipulation and data transmission.

It is a further object of the present invention to provide this apparatus, operation and method through advanced processing of acoustic signatures in the time and frequency domain to isolate and display the sound components associated with pulmonary and/or aortic heart valve closure.

It is a further object of the present invention to provide an apparatus, operation and method that is suitable for routine physical examination screening and early diagnosis of elevated pulmonic blood pressure thereby providing an opportunity for early intervention to enhance the patient's productive life.

It is a further object of the present invention to provide an apparatus, operation and method that is suitable for monitoring of systemic blood pressure in patients where use of a traditional blood pressure cuff is contraindicated.

These and other objects of the present invention will become obvious to those skilled in the art upon review of the following disclosure.

An apparatus for determining blood pressure in accordance with the present invention includes a sensor assembly comprising a housing, an electronic module, a shock dampener, a mounting means, a piezoelectric transducer, an acoustic coupling and a back cover. The sensor assembly is connected to a data acquisition module which in turn is connected to a signal processing means. The signal processing means is connected to an electronic storage means, a hard copy reproduction means, a remote connection means and a monitor. In an alternative embodiment of the invention a plurality of sensor assemblies are connected to the data acquisition module. In another alternative embodiment of the invention a means for determining an electrocardiogram is connected to the signal processing means. In yet another alternative embodiment of the invention, data acquisition module is connected to high-fidelity earphones.

The operation for determining blood pressure in accordance with the present invention includes:

1) performing start-up procedures;
2) acquiring physiologic signals;
3) acquiring ambient or background signals;
4) processing and subtracting ambient signals from physiologic signals;
5) conditioning and processing resultant data;
6) subjecting the conditioned and processed data to Fast Fourier Transformation;
7) passing the time domain components of the data through a time domain correlator and feature extraction process;
8) passing the frequency domain components of the data through a frequency domain correlator and feature extraction process;
9) comparing the time domain output and the frequency domain output to a reference pattern and feature library;
10) determining whether the time domain output and frequency domain output match known disease modalities;
11) determining whether a disease modality is indicated;
12) updating the reference pattern and feature library; and
13) providing the information regarding the disease modality to the physician so that a treatment regimen may commence.

The method for determining blood pressure in accordance with the present invention includes monitoring the sounds of the aortic and/or the pulmonary semilunar valves. Where one wishes to determine systemic pressure, the aortic semilunar valve is monitored. This is done by placing the acoustic coupling of the sensor assembly adjacent to the patient's skin at the traditional auscultation point for the aortic valve. Where one wishes to monitor pulmonary pressure, the pulmonary semilunar valve is monitored. This is done by placing the acoustic coupling of the sensor assembly in contact with the patient's skin at the traditional auscultation point for the pulmonic valve. Detected signals are manipulated in the same fashion noted in the "operation" of the present invention. The signals may be viewed and analyzed by medical personnel at any number of points during this data manipulation process

to allow for the implementation of a treatment regimen. Where the sound emitted by either semilunar valve is of a higher than normal frequency, this is indicative of increased blood pressure in the corresponding circuit; that is, an increased frequency emitted by the aortic semilunar valve is indicative of higher than normal systemic blood pressure, while an increased frequency being emitted by the pulmonary semilunar valve is indicative of higher than normal pulmonary blood pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic representation of the overall architecture and user interface of the present invention.

Figure 2a depicts an exploded, oblique view of the sensor assembly.

Figure 2b depicts an exploded, side view of the sensor assembly.

Figure 3 depicts an exploded, oblique view of an alternative embodiment of the sensor assembly.

Figure 4 depicts a circuit diagram of the electronic module, data cable and data acquisition module.

Figure 5 depicts a circuit diagram of greater detail, comprising the electronic module, data cable and data acquisition module.

Figure 6 depicts a circuit diagram of still greater detail, comprising the electronic module, data cable and data acquisition module.

Figure 7 depicts the frequency response of a tailored bandpass amplifier.

Figure 8 illustrates the simultaneous display of ECG and acoustic signal data.

Figure 9a illustrates an acoustic amplitude vs. time display mode.

Figure 9b illustrates a relative amplitude vs. frequency display mode.

Figure 9c illustrates a frequency vs. time display mode.

Figure 10 is a flow chart illustrating the operation of the present invention.

Figure 11 graphs the relationship of second heart sound frequency vs. blood pressure.

DETAILED DESCRIPTION

The present invention provides an apparatus, operation and method to passively and non-invasively measure systemic and pulmonic blood pressure through detection, identification and characterization of the acoustic signature associated with heart valve closure.

APPARATUS

Referring to Figure 1, the overall architecture of the present invention is described. Patient physiologic signals, such as acoustic vibrations or electrical impulses, are detected by sensor assembly **102**. In an alternative embodiment a plurality of sensor assemblies can be used to either simultaneously obtain signals from various locations of the body or to simultaneously obtain signals from both the patient and the environment. Sensor assembly **102** is connected to data acquisition means **103**.

Data acquisition means **103** comprises preamplifier **114**, audio amplifier **116**, and analog-to-digital converter **118**. Preamplifier **114** electronically isolates the transducer, detects the electronic signals, and sends them to audio amplifier **116** and to analog-to-digital converter **118**. Audio amplifier **116** drives one or more sets of high-fidelity earphones **120**. Analog-to-digital converter **118** samples the analog signal and converts it to a binary number for each time sample. Data acquisition means **103** is connected to signal processing means **104**.

Signal processing means **104** is a general-purpose microprocessor. Signal processing means **104**, also has means for video display of information, such as monitor **112**. Signal processing means **104** is connected to electronic data storage means **106**, operator input means **107**, hard copy reproduction means **108** and remote connection means **110**.

Various types of electronic data storage are known to those skilled in the art. In alternative embodiments electronic data storage means **106** comprises: internal hard disk drive, external hard disk drive, floppy disks, digital audio tape, magneto-optical storage or CD ROM. Likewise, various types of operator input means are known to those skilled in the art. In alternative embodiments operator input means **107** comprises: keyboard, mouse, voice detector or other means. Hard copy reproduction means **108** provides copies of images displayed on monitor **112** for purposes such as maintaining medical records, assisting

consultations, and assisting data processing and review. Remote connection means **110** is a modem. In alternative embodiments, the system of the present invention may be directly linked to a network via a network interface card or other suitable means. Thus a modem may not always be necessary.

In an alternative sensor assembly embodiment, sensor assembly **102** can detect both physiologic and background signals. In another alternative sensor assembly embodiment, one side of sensor assembly **102** comprises an audio transducer which is in contact with the skin while a second audio transducer on the opposite side faces away from the patient. This second transducer is designed to acquire ambient sounds in synchronism with the sounds reaching the transducer in contact with the patient's skin to reject common mode signals reaching both transducers. By adding the environmental signals out of phase with the signals acquired from the patient, the sounds in common to both transducers are effectively canceled. In yet another alternative sensor assembly embodiment the target frequency range for data acquisition is about 200 to 2000 Hz. In another alternative sensor assembly embodiment, the target frequency range for signal acquisition is about 400 hertz.

In an alternative preamplifier embodiment, preamplifier **114** demonstrates low-noise data acquisition and proper impedance matching.

In an alternative analog-to-digital converter embodiment analog-to-digital converter **118** has a sample rate about 4 to 48 Khz. In yet another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a sample rate of about 44 Khz. In another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a resolution of about 16 bits. In yet another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a linearity about ± 0.005 percent of full scale. In another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a sample length of about one to sixty seconds. In yet another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has an operator selectable sample length.

In an alternative earphones embodiment, earphones **120** have separate volume controls.

In an alternative signal processing means embodiment, signal processing means **104** is a computer with a central processing unit. In another alternative signal processing means

embodiment, signal processing means **104** is an IBM compatible personal computer using an INTEL processor (386, 486, Pentium), having a minimum of 8 MB RAM memory and a minimum hard disk size of 500 MB. In yet another alternative signal processing means embodiment, signal processing means **104** is a Macintosh PowerPC.

In an alternative monitor embodiment, monitor **112** has a minimum display size of 600 X 400 pixels and a minimum monitor **112** display depth of eight bits. In yet another alternative monitor embodiment, monitor **112** is a high resolution EGA or VGA color display monitor.

In an alternative signal processing means embodiment, signal processing means **104** comprises a sound card. In another alternative signal processing means embodiment, the sound card comprises a "Tahiti" multiple channel computer sound card manufactured by Turtle Beach, although sound cards such as the Pro Audio 1b (Media Vision) can also be used.

In an alternative hard copy reproduction means embodiment, hard copy reproduction means **108**, is a printer. In another alternative hard copy reproduction means embodiment, hard copy reproduction means **108** is a printer capable of generating a variety of different graphic displays. In yet another alternative hard copy reproduction means embodiment, hard copy reproduction means **108** is a laser printer.

In an alternative remote connection means embodiment, remote connection means **110** is an internal or external, high speed modem. In another alternative remote connection means embodiment, remote connection means **110** has a speed of at least 14.4 kilobytes per second.

Referring to Figure 2a, an oblique view of an embodiment of sensor assembly **102** is shown. Figure 2b depicts a side view of an embodiment of sensor assembly **102**. Housing **302** comprises a sound deadening material having sufficient mass to dampen high frequency ambient disturbances and hold the sensor assembly in contact with the patient through gravity. Housing **302** has housing front **304** and housing back **306**. Rim **308** is located on the periphery of housing front **304**. First indentation **310** runs parallel and adjacent to the inside of rim **308**. Second indentation **312** runs parallel and adjacent to the inside of first indentation **310**. Bore **312** is approximately centrally located within second indentation **312** and is shaped and sized in conformity to the shape and size of electronic module **314**.

Electronic module **314** nests within bore **312** of housing **302**. As will be further discussed, signal detection and processing circuitry are incorporated within electronic module **314**.

Shock dampener **316** is positioned adjacent to first indentation **310**. Mounting means **318** is positioned adjacent to shock dampener **316**. Transducer **320** is positioned within mounting means **318**. Transducer **320** converts detected signals into electronic signals. Acoustic coupling **322** is positioned adjacent to transducer **320**. Acoustic coupling **322** serves to dilinearize excitation response and reduce dynamic range.

Once assembled, housing **302** is closed to the ambient environment with back cover **324**. Sensor assembly **102** comprising all the individual sensor elements, is assembled and sealed to form a single complete unit.

In an alternative housing embodiment, housing **302** is composed of nickel plated aluminum, but can be any material having sufficient mass to dampen high frequency ambient disturbances and hold the sensor in contact with the patient through gravity.

In an alternative sensor assembly embodiment, when electronic module **314** nests within bore **312** of housing **302**, top **316** of electronic module **314** is flush with second indentation **312**.

In an alternative shock dampener embodiment shock dampener **316** is an "O" ring.

In an alternative mounting means embodiment, mounting means **318** is a plastic mounting ring.

In an alternative transducer embodiment, transducer **320** is a piezoelectric disk. In another alternative transducer embodiment, transducer **320** has a high impedance. In yet another alternative transducer embodiment, transducer **320** has an impedance of about 470 Kohms. In another alternative transducer embodiment, transducer **320** has high efficiency as compared with conventional electromagnet type speakers. In yet another alternative transducer embodiment, transducer **320** is ultra thin and lightweight. In another alternative transducer embodiment, transducer **320** has a frequency range of about 500 - 20,000 Hz. In yet another alternative transducer embodiment, transducer **320** has a capacitance at 120 Hz of about 60 ± 30 % nF. In another alternative transducer embodiment, transducer **320** current leakage is limited to about one micro ampere.

In an alternative acoustic coupling embodiment, acoustic coupling **322** is impedance matched, and serves to provide a low-loss acoustic transmission coupling between the skin of

the patient and transducer **320**, thereby minimizing signal loss across the subject-detector interface. In another alternative acoustic coupling embodiment, acoustic coupling **322** is a parametric acoustic transconductor. In yet another acoustic coupling embodiment, acoustic coupling **322** has a high conduction coefficient. In another alternative acoustic coupling embodiment, acoustic coupling **322** is made of latex foam. In yet another alternative acoustic coupling embodiment, acoustic coupling **322** is logarithmically attenuated, having low transmission at low frequencies and high transmission at high frequencies.

Referring to Figure 3 an oblique exploded view of an alternative embodiment of sensor assembly **102** is shown. Housing **402** comprises a sound deadening material having sufficient mass to dampen high frequency ambient disturbances and hold the sensor assembly in contact with the patient through gravity. Housing **402** has housing front **404** and housing back **406**. First rim **408** is located on the periphery of housing front **404**. Second rim **410** is located on the periphery of housing back **406**. First indentation **412** runs parallel and adjacent to the inside of first rim **408**. Second indentation **414** runs parallel and adjacent to the inside of first indentation **412**. Third indentation **416** runs parallel and adjacent to the inside of second rim **410**. Fourth indentation **418** runs parallel and adjacent to the inside of third indentation **416**. First bore **420** is approximately centrally located within second indentation **414** and is shaped and sized in conformity to the shape and size of first electronic module **422**. Second bore **440** is approximately centrally located within fourth indentation **418** and is shaped and sized in conformity to the shape and size of second electronic module **442**. First electronic module **422** nests within first bore **420** of housing **402**. Second electronic module **442** nests within second bore **440** of housing **402**. As will be further discussed, signal detection and processing circuitry are incorporated within first and second electronic module **422, 442**.

First shock dampener **424** is positioned adjacent to first indentation **412**. Second shock dampener **426** is positioned adjacent to third indentation **416**. First mounting means **428** is positioned adjacent to first shock dampener **424**. Second mounting means **430** is positioned adjacent to second shock dampener **426**. First transducer **432** is positioned within first mounting means **428**. Second transducer **434** is positioned within second mounting means **430**. First transducer **432**, converts detected physiologic signals into electronic signals. Second transducer **434**, converts detected environmental or background signals into

electronic signals. First acoustic coupling **436** is positioned adjacent to first transducer **432**. Second acoustic coupling **438** is positioned adjacent to second transducer **434**. First and second acoustic coupling **436**, **438** serve to dilinearize excitation response and reduce dynamic range.

In an alternative housing embodiment, housing **402** is composed of nickel plated aluminum.

In an alternative shock dampener embodiment, first and second shock dampener **424**, **426** is an "O" ring.

In an alternative mounting means embodiment, first and second mounting means **428**, **430** is a plastic mounting ring.

In an alternative transducer embodiment, first and second transducer **432**, **434** is a piezoelectric disk. In another alternative transducer embodiment, first and second transducer **432**, **434** has a high impedance. In yet another alternative transducer embodiment, first and second transducer **432**, **434** has an impedance of about 470 Kohms. In another alternative transducer embodiment, first and second transducer **434**, **434** has high efficiency as compared with conventional electromagnet type speakers. In yet another alternative transducer embodiment, first and second transducer **432**, **434** is ultra thin and lightweight. In another alternative transducer embodiment, first and second transducer **432**, **434** has a frequency range of about 5 - 2,000 Hz. In yet another alternative transducer embodiment, first and second transducer **432**, **434** has a capacitance at 120 Hz of about 60 ± 30 % nF. In another alternative transducer embodiment, first and second transducer **432**, **434** current leakage is limited to about one micro ampere.

In an alternative acoustic coupling embodiment, first and second acoustic coupling **436, 438**, is impedance matched, and serves to provide a low-loss acoustic transmission coupling between the skin of the patient and first transducer **432**, thereby minimizing signal loss across the subject-detector interface. In another alternative acoustic coupling embodiment, first and second acoustic coupling **436, 438** is a parametric acoustic transconductor. In yet another acoustic coupling embodiment, first and second acoustic coupling **436, 438** has a high conduction coefficient. In another alternative acoustic coupling embodiment, first and second acoustic coupling **436, 438** is made of latex foam. In yet another alternative acoustic coupling embodiment, acoustic coupling **322** is logarithmically

attenuated, having low transmission at low frequencies and high transmission at high frequencies.

Referring to Figure 4, electronic module **314**, transducer **320**, data cable **502**, and data acquisition module **504** of the present invention are shown in schematic form. In combination, first resistor **506**, semiconductor device **508**, second resistor **510**, and first capacitor **512** comprise electronic module **314**. Electronic module **314** performs functions such as signal amplification, and filtering. Transducer **320** is connected in parallel with first resistor **506**, second resistor **510**, first capacitor **512**, and semiconductor **508**. Semiconductor **508** serves to modulate current. First capacitor **512** provides gain and source decoupling for semiconductor **508**.

In an alternative first resistor embodiment, first resistor **506** provides a matching load to transducer **320**. In another alternative first resistor embodiment first resistor **506** has a resistance of 470 Kohms.

In an alternative second resistor embodiment, second resistor **510** is about 10 Kohms.

In an alternative semiconductor embodiment, semiconductor **508** is field effect transistor. In another alternative semiconductor embodiment, semiconductor **508** is a field effect transistor with an N-type base.

In an alternative first capacitor embodiment, first capacitor **512** is 60 microfarads and is connected to ground.

Figure 5 depicts a circuit diagram of the electronic module, data cable and data acquisition module in greater detail. The circuit comprises electronic module **314**, transducer **320**, data cable **502**, and data acquisition module **504**. Data cable **502** couples electronic module **314** to data acquisition module **504**. Data acquisition module **504** comprises an amplifier. As depicted in Fig. 5, highpass filter **606** is followed by lowpass filter **608** having a DC injection point. The amount of DC injection is made variable by value selection of variable resistor **610**. In an alternative value selection embodiment, value selection is determined by the practitioner. In yet another alternative value selection embodiment, value selection is determined automatically by the signal processing means in conformity with predetermined parameters.

In an alternative data cable embodiment, data cable **502** is twisted pair **602**, wherein two insulated wires are twisted forming a flexible line without the use of spacers. In another

alternative data cable embodiment, data cable **502** is shielded pair **604**, wherein two parallel conductors are separated from each other and surrounded by a solid dielectric. In this alternative embodiment, the conductors are contained within a copper-braid tubing that acts as a shield. The assembly is covered with a rubber or flexible composition coating to protect the line against moisture and friction. There are two advantages of this alternative embodiment: (1) the capacitance between each conductor and ground is uniform along the entire length of the line; and (2) the wires are shielded against pickup of stray electric fields. In yet another alternative embodiment shielded pair **604** data cable **502** is connected to sensor housing **610** and to ground as a means for reducing electrical noise and increasing patient safety.

In an alternative data acquisition module embodiment, data acquisition module **504** has a low frequency response from about 10 Hz to a crossover point at 100 Hz, rising to a level 20 dB higher from about 600 Hz to 2 KHZ, then declining steadily beyond that point. In another alternative data acquisition module embodiment, data acquisition module **504** comprises a voltage gain, variable from zero to fifty, allowing recovery of low-level sounds from 600 to about 2000 Hz while preserving the ability to measure low-frequency signals having a relatively high amplitude, without amplifier saturation.

In an alternative highpass filter embodiment, highpass filter **606** has a gain of about 7, and lowpass filter **608** drives an output amplifier with a gain of about 7. In another alternative highpass filter embodiment the overall voltage gain available with the gain potentiometer at maximum will be about 50. An advantage of this alternative embodiment is the ability to reject a narrow range of frequencies in a notch caused by the phase delay in the components of highpass filter **606**. In an alternative highpass filter embodiment this notch is set at 100 Hz. In another alternative highpass filter embodiment this notch is set at about 50 - 60 Hz, thereby providing a measure of hum rejection

Figure 6 depicts a circuit diagram of the electronic module, data cable and data acquisition module in greater detail. The circuit comprises electronic module **314**, transducer **320**, data cable **502**, and data acquisition module **504**. Three stage resistor/capacitor network **702** gives a total of about 180 degrees of phase shift at a design frequency of about 100 Hz that is related to the combined resistor/capacitor time constants of the network. Field effect transistor **508** input is AC-coupled to the four-pole lowpass filter **608** formed by a single 747-

type operational amplifier pair.

Figure 7 depicts an idealized shape of an amplifier having low-frequency response from first point **802** to crossover point **804** and having higher frequency response of predetermined level **806**, from second point **808** to third point **810**. In an alternative embodiment, first point **802** is about 10 Hz, crossover point **804** is about 100 Hz, predetermined level **806** is about 20 dB, second point **808** is about 600 Hz and third point **810** is about 2 Khz. In yet another alternative embodiment, crossover point **804** is about 60 Hz.

Figure 8 further depicts the response of the tailored bandpass amplifier, plotting amplitude **902** vs. frequency **904** of basic heart sounds **906** and sounds of interest **908**. In alternative embodiments, the response of sounds of interest **908** may be set at varying levels **910**.

Figure 9 depicts the simultaneous display of electrocardiogram and sonospectrography data. In the simultaneous display mode, the present invention provides for plotting electrocardiogram data and sonospectrography data as a function of intensity **1002** and time **1004**, with digital markers **1006** to allow the visual correlation of points of signal activity that may be common to both signals. As an example, the electrocardiogram pulse at **1008** can be visually correlated with a select part of the acoustic signal **1010** and differentially measured to within 23 millionths of a second. This allows an operator who may be less familiar with acoustic signatures to correlate the electrocardiogram signal, which may be well understood, with the acoustic signal.

Referring to Figures 10a, 10b, and 10c, the display methodology of the present invention is shown. The present invention provides a means to simultaneously display the signal of interest in a variety of different forms. In Figure 10a, the signal of interest of the present invention is presented as a simple time series, with acoustic amplitude **1102** on the vertical scale and time **1104** on the horizontal scale. In Figure 10b, the signal of interest of the present invention is presented as a time and frequency display, with relative amplitude **1106** of each slice of the frequency spectrum on the vertical scale and frequency spectrum **1108** on the horizontal display. In Figure 10c, the signal of interest of the present invention is presented with frequency **1110** on the vertical axis, time **1112** on the horizontal axis, and relative amplitude plotted in different color hues (not shown) and/or grey scale intensity.

Having thus described the basic concept of the apparatus of the invention, it will be

readily apparent to those skilled in the art that the foregoing detailed disclosure is intended to be presented by way of example only, and is not limiting. Various alterations, improvements and modifications will occur and are intended to those skilled in the art, but are not expressly stated herein. For example, while cardiovascular monitoring is a key aspect of the invention, the techniques described herein are equally applicable to the monitoring of other body organs and regions of the body of both humans and animals and thus may also find utility in the veterinary sciences. These modifications, alterations and improvements are intended to be suggested hereby, and are within the spirit and scope of the invention.

OPERATION

Figure 11 depicts the operation of the apparatus of the present invention with associated hardware and software. At step **1202**, start-up procedures are performed such as initialization, calibration, sensor selection, patient parameter input, and buffer clearing, among others. Upon completion of these start-up procedures steps **1204** and **1206** are initiated. At step **1204**, sensor **102** provides patient physiologic signals for signal processing. In an alternative embodiment, sensor **102** can include electrocardiogram sensors and acoustic sensors. At step **1206** acoustic sensors are used to detect background or ambient noise.

Next, at step **1208**, the detected signals are passed to individual data acquisition modules which contain means for signal filtering, impedance matching, amplification, and buffering. These functions are performed by the components of the circuitry illustrated in Figs. 4-6.

At step **1210**, the signals from the ambient noise acoustic sensor acquired in step **1206**, are processed and subtracted from the signals from the desired sensor of step **1204** in a noise cancellation process to reduce the effect of ambient noise from the patient's environment.

At step **1212**, the signal undergoes additional signal conditioning and processing. The purpose of this conditioning step is to convert the analog signal to digital, provide adjustable decimation with a sampling rate suitable to avoid biasing, provide adjustable smoothing, averaging and peak holding. In an alternative embodiment the signal conditioning and processing of step **1212** is performed by a sound card which typically has the following

capabilities: (1) a sample rate selectable from about 4 K to 44 K; (2) a sample size of about 16 bits; (3) capable of analog to digital conversion; (4) capable of digital to analog conversion; and (5) possesses IBM computer bus compatibility such as ISA, EISA, PCI, etc. In yet another alternative embodiment the sound card used comprises a "Tahiti" multiple channel Sound Card manufactured by Turtle Beach. Step **1230** allows for the intermediate output and display of the desired signal following the signal conditioning and processing of step **1212**. The display is accomplished by selection of a desired display mode and subsequent display on the monitor **112**. The output of step **1212** is of a time series and is suitable for display selection as in Figure 10a.

At step **1214**, the digitized and conditioned data is subjected to a sliding fast Fourier transformation. The output of step **1214** is of time and frequency and is suitable for display selection according to Figures 10b or 10c.

At step **1216**, time domain components of the data passes through a time domain correlator and feature extraction process. In a similar fashion, in step **1218**, the frequency domain components of the data passes through a frequency domain correlator and feature extractor. In step **1220**, the outputs from the time domain correlator and feature extraction process of step **1216** and the frequency domain correlator and feature extractor of step **1218** are compared to a reference pattern and feature library, to determine whether the features contained within the signal of interest match known disease modalities as recorded and maintained within the reference pattern and feature library.

At step **1222**, the outputs from the time domain correlator and feature extraction process of step **1216**, the frequency domain correlator and feature extractor process of step **1218** and the results from the reference pattern and feature library comparison of step **1220** are subjected to a recognition logic decision, where a determination is made as to whether a disease or adverse condition is indicated. At step **1224**, the new disease modality indicated in the recognition logic decision of step **1222** is then used to update the reference pattern and feature library of step **1220**. In step **1226** a desired display mode such as depicted in Figures 10a, 10b and 10c is chosen for subsequent display on the monitor **112**. At step **1228** the process is either terminated at step **1240** or begun anew at step **1202**.

The preceding descriptions of the operation of the present invention are merely illustrative. In various embodiments of the disclosed invention operational steps may be

added, eliminated, performed in parallel or performed in a differing order.

METHOD

Sonospectrography can be used as a primary source of auscultatory information in a routine physical examination or in population screening. Sonospectrography can be used in cardiology and general medicine for the detection of functional and organic disorders of the heart such as congenital defects, valve function, diseases of the pericardium and myocardium and systemic and pulmonary hypertension. Sonospectrography can also be used as a traditional stethoscope to capture sounds generated by other organs, such as the lungs, trachea, larynx, liver and carotid arteries.

Elevated blood pressure has a number of causes. Regardless of the cause, however, recent testing at the Uniformed Services University of Health Sciences shows that there is a change in the frequency spectrum of both the aortic and pulmonary semilunar valve sounds that is directly correlated to change in blood pressure of the associated systemic or pulmonary circulatory system. This correlation was shown to be both measurable and repeatable in testing on animals having systemic and pulmonary circulatory systems comparable to the human system.

Elevated blood pressure increases back pressure at associated heart valves. This increased back pressure results in more rapid closure of the heart valves and a resultant audible "snap" of the valve leaflets. The acoustic signature that is associated with those heart valve sounds has elevated frequency components as compared to the signature associated with heart valves operating under normal blood pressures. As the blood pressure increases, this frequency component also increases. It has been determined that this change in the frequency component is transitory and returns to normal when the blood pressure returns to normal.

Thus, where the sound emitted by the aortic semilunar valve is of an increased frequency, this is indicative of higher systemic blood pressure. Similarly, where the sound emitted by the pulmonary semilunar valve is of an increased frequency, this is indicative of higher pulmonic blood pressure. Through the use of the apparatus of the present invention, it is possible to detect and record sounds originating from the aortic and pulmonary semilunar

valves.

In practice, a sensor assembly is placed in contact with the patient. One side of the sensor assembly contains an acoustic coupler that is placed in contact with the patient's skin at the traditional auscultation point for the valve of interest, while a second acoustic coupler on the opposite side faces away from the patient. This second acoustic coupler is designed to acquire background sounds in synchronism with the acoustic coupler in contact with the patient's skin to reject common mode signals reaching both couplers. While breathing normally the sounds of the aortic and/or pulmonary semilunar valves are acquired, preamplified and sent to a plurality of locations.

One analog signal is sent directly to an audio amplifier and high fidelity earphones. A second analog signal is sent through a gain control potentiometer to an analog to digital converter. The data is digitized and displayed in real time on a monitor. Visual feedback from the monitor allows a precise setting of the gain control by the physician for the optimum acquisition of data. In an alternative embodiment, an electronic strip chart is used in the precise setting of the gain control. The physician adjusts gain control to maximize the dynamic range of the captured signal.

In one embodiment, sounds are filtered normally. In an alternative embodiment, sounds are filtered to de-emphasize interfering responses prior to being sent to the earphones or the analog to digital converter. Data can be stored digitally, recalled for future analysis or transmitted to another location.

Referring to Figure 12, data from recent in-vivo testing on animal subjects at the Uniformed Services University of Health Sciences is shown. The subject had a pressure catheter emplaced to provide actual pressure readings, and the present invention detected, and processed the acoustic signature data from the second heart sounds. Figure 12 plots the relationship between second heart sound A2 **1302**, and blood pressure **1304**. As shown, where there is a rise in the frequency of second heart sound **1302**, there is a corresponding rise in systolic pressure **1306**, mean pressure **1308** and diastolic pressure **1310**.

The subject whose pressure/frequency relationship is depicted in Figure 12, had a resting systolic pressure of about 120 mm Hg, a resting diastolic pressure of about 77 mm Hg, and a predominant second heart sound frequency of 28.5 Hz. The mean blood pressure was thus about 90 mm Hg at 28.5 Hz. As the subject's blood pressure was artificially increased,

the associated frequency components of the second heart sound correspondingly increased. Systolic pressure **1306** of the subject reached about 165 mm Hg, diastolic pressure **1310** reached about 85 mm Hg, and frequency of second heart sound **1302** reached 36. Mean pressure **1308** reached about 115 mm Hg. The slope of this mean pressure/frequency curve is approximately 2 mm Hg per Hz. This pressure/frequency correlation was demonstrated in each animal subject tested.

Across a population, measurement of the sound frequency associated with the closure of the aortic and pulmonary semilunar valves will allow an estimate of the mean systemic and pulmonary blood pressure. Specifically, using a range of pressure/frequency curves collected from population samples, the present invention will allow an estimate of the mean systemic and pulmonary pressure with a passive and non-invasive acoustic measurement of the acoustic signature of the semilunar valve closure. As an example, if the mean pressure data curve **1307** in Figure 12 presented an accumulated average from the population, then measurement of a pulmonary semilunar valve closure sound frequency of 36 Hz **1309** would provide an estimate that the mean pulmonic pressure was 115 mm Hg **1311**. In an otherwise asymptomatic patient, this might provide sufficient clinical justification for use of an invasive blood pressure catheter, with the attendant risk and cost, to confirm the pulmonic pressure.

Although the method of the present invention has been described in detail for purpose of illustration, it is understood that such detail is solely for that purpose, and variations can be made therein by those skilled in the art without departing from the spirit and scope of the invention. The apparatus, operation and method of the present invention is defined by the following claims.

WHAT IS CLAIMED IS:

1. An apparatus for monitoring blood pressure comprising:

a means for detecting audio signals;

a means for signal processing connected to the signal detecting means;

a means for signal storage connected to the signal processing means; and

a means for monitoring, connected to the signal processing means.

2. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the audio signal detecting means is a sensor assembly.

3. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the audio signal detecting means is a plurality of sensor assemblies.

4. An apparatus for monitoring blood pressure as claimed in claim 2, wherein the sensor assembly comprises:

a housing having a front and a back;

an electronic module connected to the housing;

a shock dampener connected to the front of the housing;

a means for mounting connected to the housing;

a transducer connected to the mounting means;

an acoustic coupling connected to the transducer; and

a cover connected to the back of the housing.

5. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the housing further comprises a sound deadening material.

6. An apparatus for monitoring blood pressure as claimed in claim 5, wherein the housing further comprises nickel plated aluminum.

7. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the housing further comprises:

a rim having an inside and an outside, located on the periphery of the front of the housing;

a first indentation having an inside and an outside, that runs parallel and adjacent to the inside of the rim;

a second indentation that runs parallel and adjacent to the inside of the first

indentation; and

a bore that is approximately centrally located within the second indentation.

8. An apparatus for monitoring blood pressure as claimed in claim 7, wherein the electronic module nests within the bore.

9. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the shock dampener is an "O" ring.

10. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the mounting means is a plastic mounting ring.

11. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the transducer is a piezoelement.

12. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the acoustic coupling is a parametric acoustic transconductor.

13. An apparatus for monitoring blood pressure as claimed in claim 12, wherein the parametric acoustic transconductor comprises latex foam.

14. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the signal processing means is a computer with a central processing unit.

15. An apparatus for monitoring blood pressure as claimed in claim 14, wherein the computer with a central processing unit is an IBM compatible personal computer.

16. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for signal storage further comprises an array of disks.

17. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for signal storage further comprises an internal hard disk drive.

18. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for signal storage further comprises an internal hard disk drive.

19. An apparatus for monitoring blood pressure as claimed in claim 1, further comprising:

a means for hard copy reproduction connected to the signal processing means.

20. An apparatus for monitoring blood pressure as claimed in claim 19, wherein the means for hard copy reproduction further comprises a printer.

21. An apparatus for monitoring blood pressure as claimed in claim 1, further comprising:

a means for remote connection connected to the signal processing means.

22. An apparatus for monitoring blood pressure as claimed in claim 21, wherein the means for remote connection further comprises a modem.

23. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for monitoring further comprises a high resolution EGA color display monitor.

24. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for monitoring further comprises a high resolution VGA color display monitor.

25. An apparatus for monitoring blood pressure as claimed in claim 1, further comprising:

a means for data acquisition connected to the signal detection means and the signal processing means.

26. An apparatus for monitoring blood pressure as claimed in claim 25, wherein the means for data acquisition comprises an amplifier.

27. An apparatus for monitoring blood pressure as claimed in claim 26, wherein the amplifier comprises a tailored bandpass amplifier.

28. An apparatus for monitoring blood pressure as claimed in claim 27, wherein the tailored bandpass amplifier comprises a low frequency response from a predetermined first point to a predetermined second point, and a higher frequency response of a predetermined level, from the predetermined second point to a predetermined third point.

29. An apparatus for monitoring blood pressure as claimed in claim 28, wherein the predetermined level is about 20 dB.

30. An apparatus for monitoring blood pressure as claimed in claim 28, wherein the predetermined first point is about 100 Hz, the predetermined second point is about 100 Hz and the predetermined third point is about 600 Hz.

31. An apparatus for monitoring blood pressure as claimed in claim 28, where in the predetermined second point is about 60 Hz.

32. A method of determining blood pressure comprising:

performing initialization procedures;

acquiring physiologic signals;

acquiring background signals;

subtracting background signals from physiologic signals creating physiologic data;

processing physiologic data forming a time domain output and a frequency domain data output;

comparing the time domain output and the frequency domain output with a reference pattern and feature library; and

determining if a disease modality is indicated.

33. A method of determining blood pressure as claimed in claim 32, wherein performing initialization further comprises:

initializing system;

calibrating system;

selecting sensors;

inputting patient parameters; and

clearing buffers.

34. A method of determining blood pressure as claimed in claim 32, wherein acquiring physiologic signals comprises acquiring acoustic signals.

35. A method of determining blood pressure as claimed in claim 32, wherein acquiring physiologic signals comprises acquiring electric signals.

36. A method of determining blood pressure as claimed in claim 32, wherein the physiologic signals are in an analog form, further comprising:

converting, the physiologic signals from the analog form to a digital form.

37. A method of determining blood pressure as claimed in claim 32, wherein the background signals are in an analog form, further comprising the step:

converting the background signals from the analog form to a digital form.

38. A method of determining blood pressure as claimed in claim 32, wherein processing further comprises:

applying signal conditioning and time domain averaging to the physiologic data forming conditioned and averaged data;

formatting the conditioned and averaged data in an array creating formatted data;

aligning and normalizing formatted data, creating aligned and formalized data;

normalizing and integrating the aligned and formalized data, creating normalized and integrated data, wherein said normalized and integrated data has time domain components and frequency domain components;

passing the time domain components of the normalized and integrated data through a time domain correlator and feature extraction process; and

passing the frequency domain components of the normalized and integrated data through a frequency domain correlator and feature extractor, creating the time domain output and the frequency domain output.

39. A method of determining blood pressure as claimed in claim 38, further comprising:

displaying the formatted data on a monitor.

40. A method of determining blood pressure as claimed in claim 38, further comprising:

displaying the aligned and normalized data on a monitor.

41. A method of determining blood pressure as claimed in claim 38, further comprising:

displaying the normalized and integrated data on a monitor.

42. A method of determining blood pressure as claimed in claim 32, further comprising:

updating the reference pattern and feature library.

43. A method of determining systemic blood pressure using sonospectrography analysis comprising:

monitoring the frequency of a sound emitted by the aortic semilunar valve, wherein the sound is detected using a sensor assembly, to monitor physiologic signals, the sensor assembly comprising:

a housing having a front and a back;

an electronic module connected to the housing;

a shock dampener connected to the front of the housing;

a means for mounting connected to the housing;

an acoustic coupler connected to the mounting means;

a transducer connected to the acoustic coupler; and

a cover connected to the back of the housing;

processing the physiologic signals, the processing comprising:

applying signal conditioning and time domain averaging to the physiologic

signals to form conditioned and averaged data;

formatting the conditioned and averaged data in an array to create formatted data;

aligning and normalizing formatted data, to create aligned and formalized data;

normalizing and integrating the aligned and formalized data, to create normalized and integrated data that has time domain components and frequency domain components;

passing the time domain components of the normalized and integrated data through a time domain correlator and feature extraction process;

passing the frequency domain components of the normalized and integrated data through a frequency domain correlator and feature extractor, to create a time domain output and a frequency domain output;

comparing time domain output and the frequency domain output with a reference pattern and feature library; and

determining if a disease modality is indicated.

44. A method of determining systemic blood pressure using sonospectrography analysis as claimed in claim 43, further comprising:

acquiring background signals; and

subtracting background signals from physiologic signals.

45. A sensor assembly for detecting physiological sounds comprising:

a housing having a front and a back;

an electronic module connected to the housing;

a shock dampener connected to the front of the housing;

a means for mounting connected to the shock dampener;

an acoustic coupler connected to the mounting means;

a transducer connected to the acoustic coupler; and

a cover connected to the back of the housing.

46. A sensor assembly as claimed in claim 45, wherein the housing further comprises a sound deadening material.

47. A sensor assembly as claimed in claim 46, wherein the housing further comprises nickel plated aluminum.

48. A sensor assembly as claimed in claim 45, wherein the housing further comprises:

a rim having an inside and an outside, that is located on the periphery of the front of the housing;

a first indentation having an inside and an outside, that runs parallel and adjacent to the inside of the rim;

a second indentation that runs parallel and adjacent to the inside of the first indentation; and

a bore, that is approximately centrally located within the second indentation.

49. A sensor assembly as claimed in claim 48, wherein the electronic module nests within the bore.

50. A sensor assembly as claimed in claim 45, wherein the shock dampener is an "O" ring.

51. A sensor assembly as claimed in claim 45, wherein the mounting means is a plastic mounting ring.

52. A sensor assembly as claimed in claim 45, wherein the transducer is a piezoelement.

53. A sensor assembly as claimed in claim 52, wherein the acoustic coupling is a parametric acoustic transconductor.

54. A sensor assembly as claimed in claim 53, wherein the parametric acoustic transconductor comprises latex foam.

55. A sensor assembly for detecting physiological sounds comprising:

a housing, having a front, a back, and an interior;

an electronic module that nests in the interior of the housing;

a first shock dampener connected to the front of the housing;

a first mounting means connected to the first shock dampener;

a transducer connected to the first mounting means;

a first acoustic coupling connected to the transducer;

a second shock dampener connected to the back of the housing;

a second mounting means connected to the second shock dampener;

a second transducer connected to the second mounting means; and

a second acoustic coupling connected to the second transducer.

56. A sensor assembly as claimed in claim 55, wherein the housing further comprises a sound deadening material.

57. A sensor assembly as claimed in claim 56, wherein the housing further comprises nickel plated aluminum.

58. A sensor assembly as claimed in claim 55, wherein the housing further comprises:

a first rim having an inside and an outside, that is located on the periphery of the front of the housing;

a first indentation having an inside and an outside, that runs parallel and adjacent to the inside of the first rim;

a second indentation that runs parallel and adjacent to the inside of the first indentation;

a bore, that is approximately centrally located within the second indentation;

a second rim having an inside and an outside, that is located on the periphery of the back of the housing;

a third indentation having an inside and an outside, that runs parallel and adjacent to the inside of the second rim; and

a fourth indentation, that runs parallel and adjacent to the inside of the third indentation.

59. A sensor assembly as claimed in claim 58, wherein the electronic module nests within the bore.

60. A sensor assembly as claimed in claim 58, wherein the first shock dampener is an "O" ring and the second shock dampener is an "O" ring.

61. A sensor assembly as claimed in claim 58, wherein the first mounting means is a plastic mounting ring and the second mounting means is a plastic mounting ring.

62. A sensor assembly as claimed in claim 58, wherein the first transducer is a piezoelement and the second transducer is a piezoelement.

63. A sensor assembly as claimed in claim 58, wherein the first acoustic coupling is a parametric acoustic transconductor and the second acoustic coupling is a parametric acoustic transconductor.

64. A sensor assembly as claimed in claim 58, wherein the parametric acoustic transconductor comprises latex foam.

65. An apparatus for determining blood pressure comprising:

an acoustic coupling, wherein the acoustic coupling provides a low-loss acoustic transmission coupling between skin and a piezoelectric transducer.

66. An apparatus for determining blood pressure as claimed in claim 65, wherein the acoustic coupling is a parametric acoustic transconductor.

67. An apparatus for determining blood pressure as claimed in claim 65, wherein the acoustic coupling has a high conduction coefficient.

68. An apparatus for determining blood pressure as claimed in claim 65 wherein the acoustic coupling comprises latex foam.

69. An apparatus for monitoring blood pressure comprising:

an acoustic coupling;

a transducer connected to the acoustic coupling;

an electronic module connected to the transducer;

a data acquisition module connected to the electronic module; and

a data cable connected to the electronic module and the data acquisition module.

70. An apparatus for monitoring blood pressure as claimed in claim 69, wherein the data cable is a twisted shielded pair.

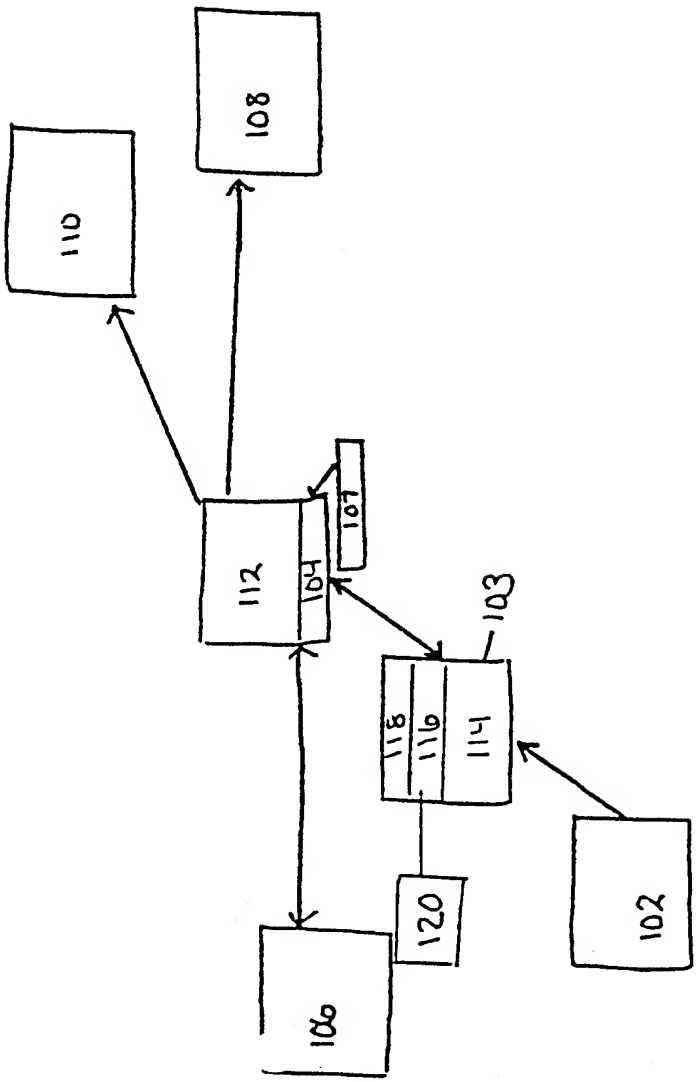

Fig. 1

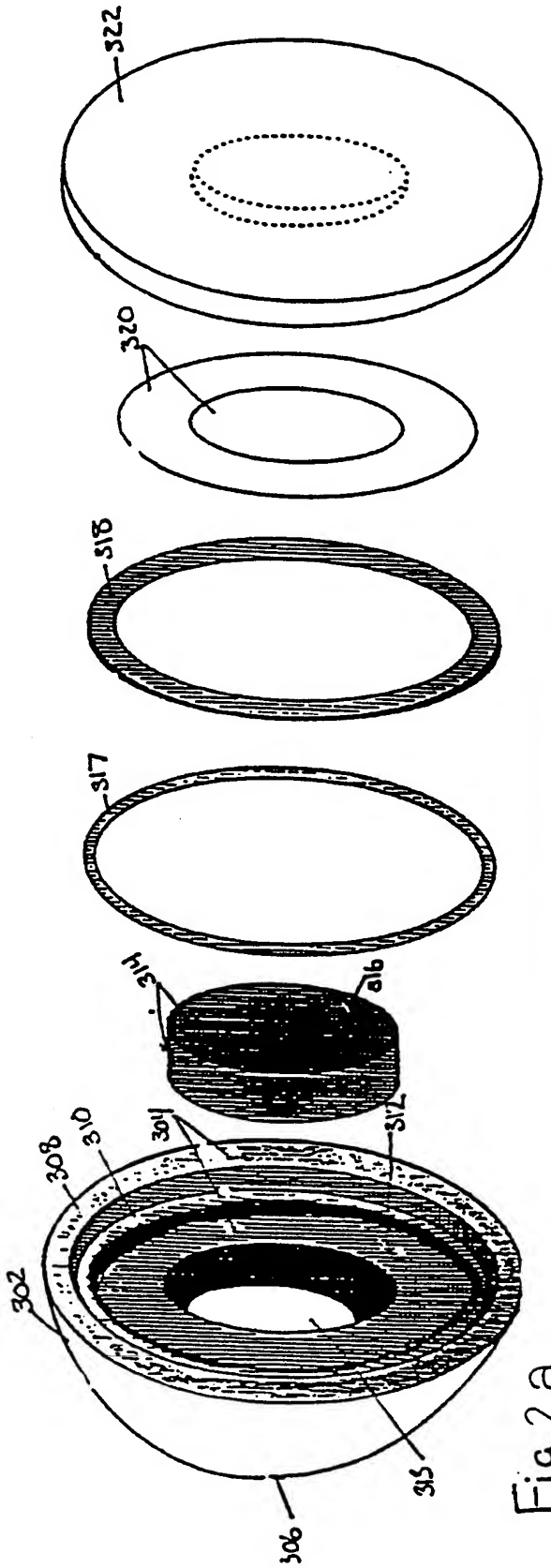
322
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Fig.2a

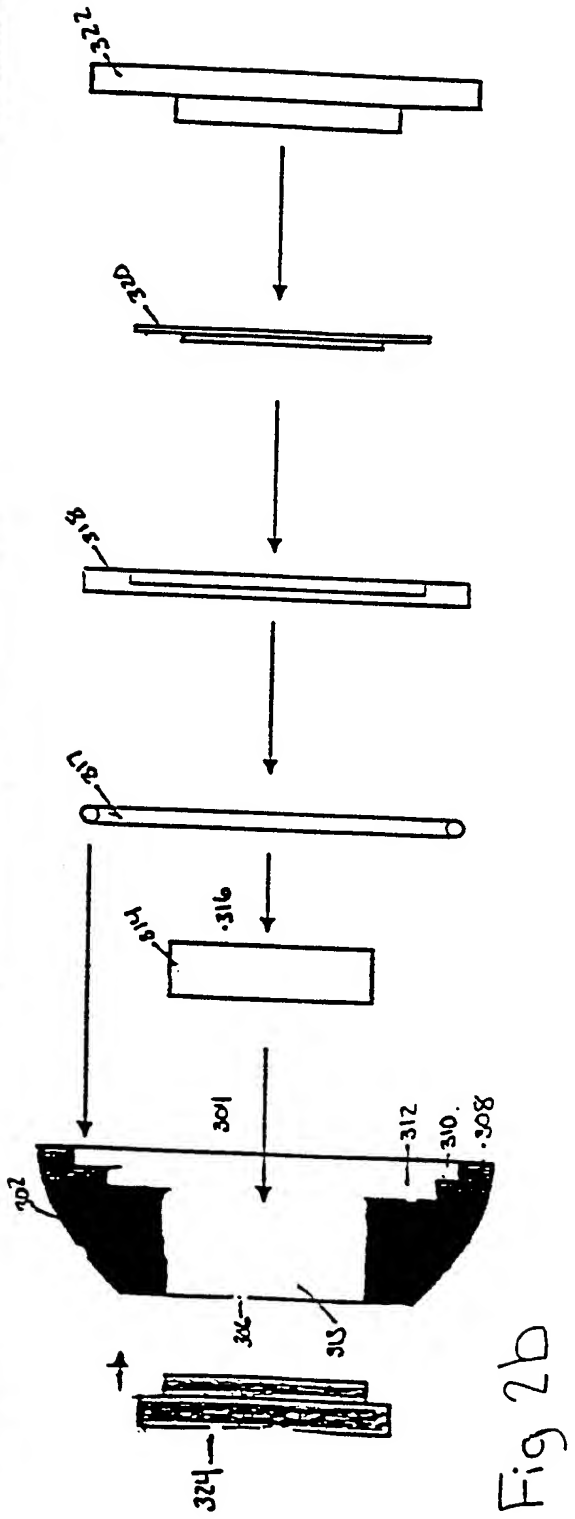
322
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Fig 2b

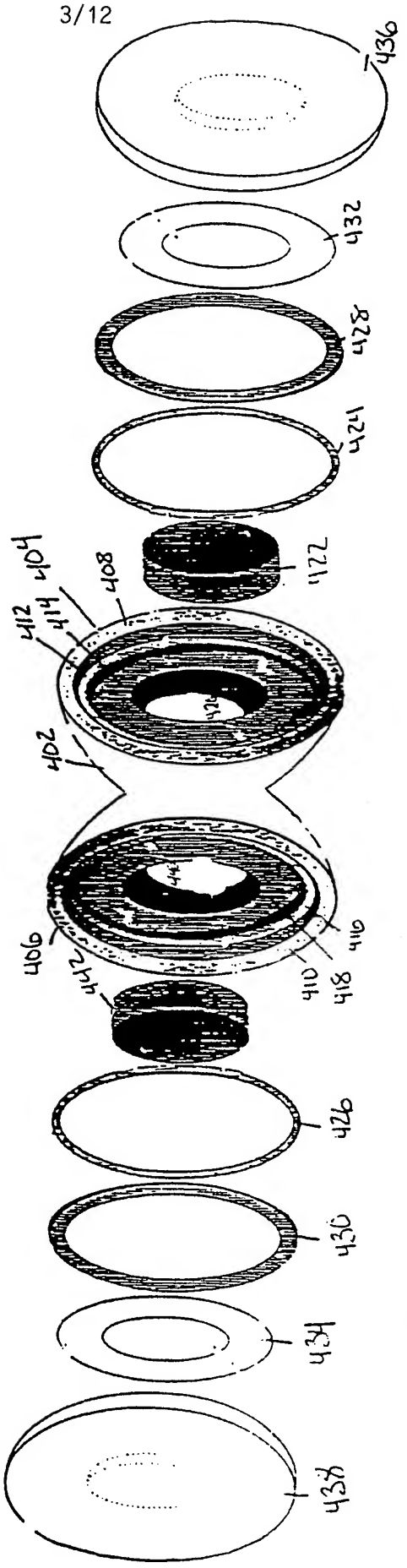
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Fig. 3

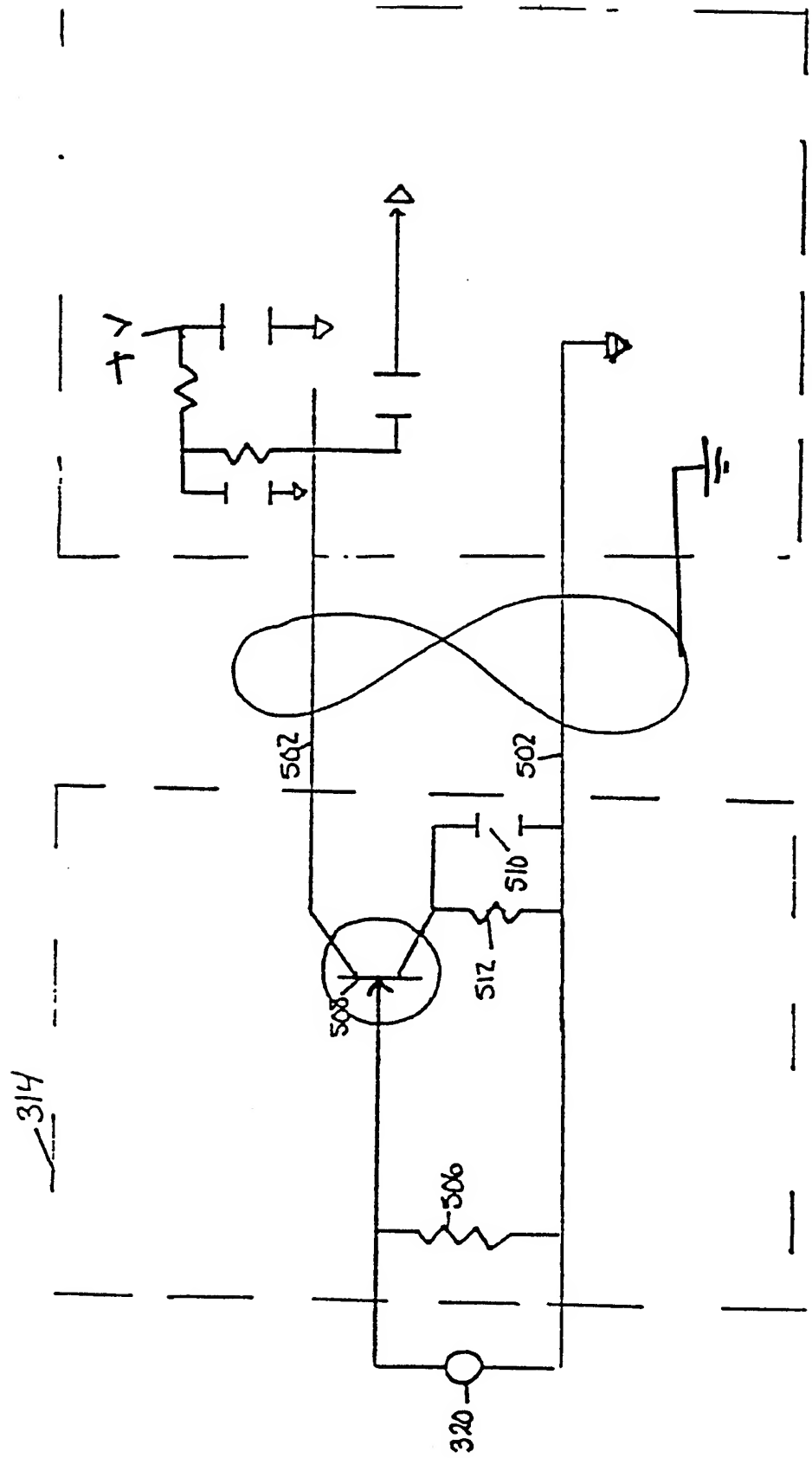


Fig. 4

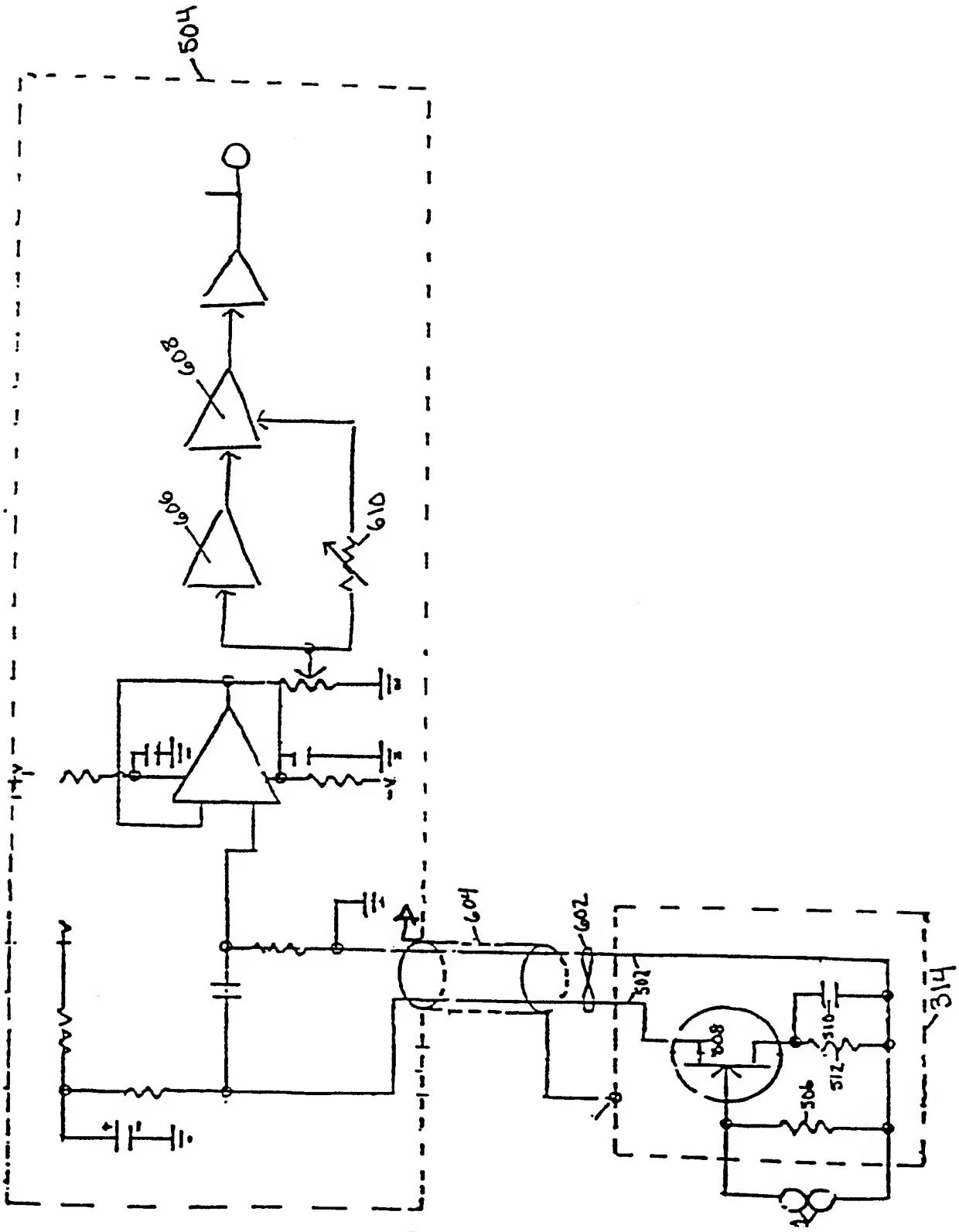


Fig. 5

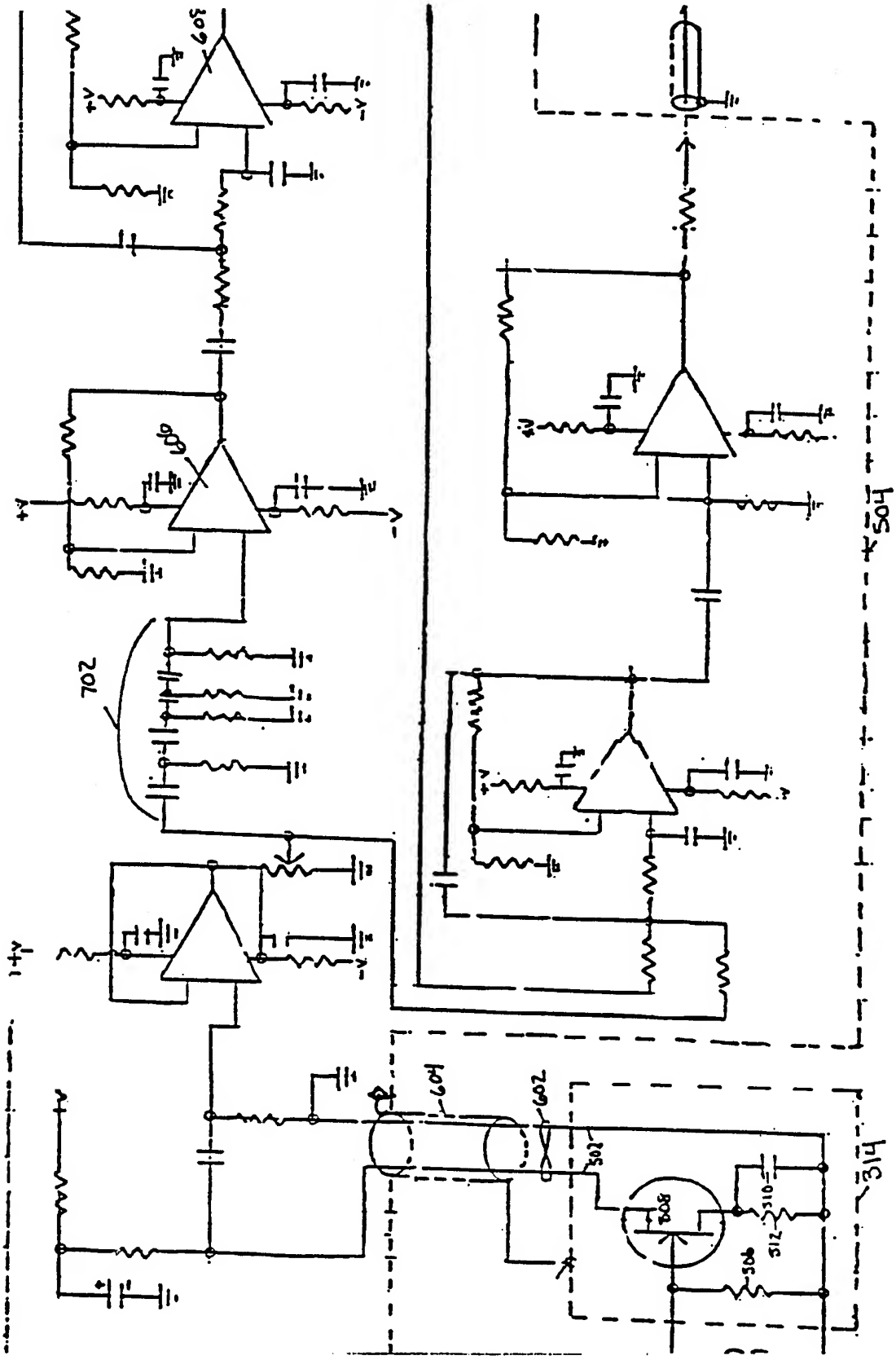


Fig. 6

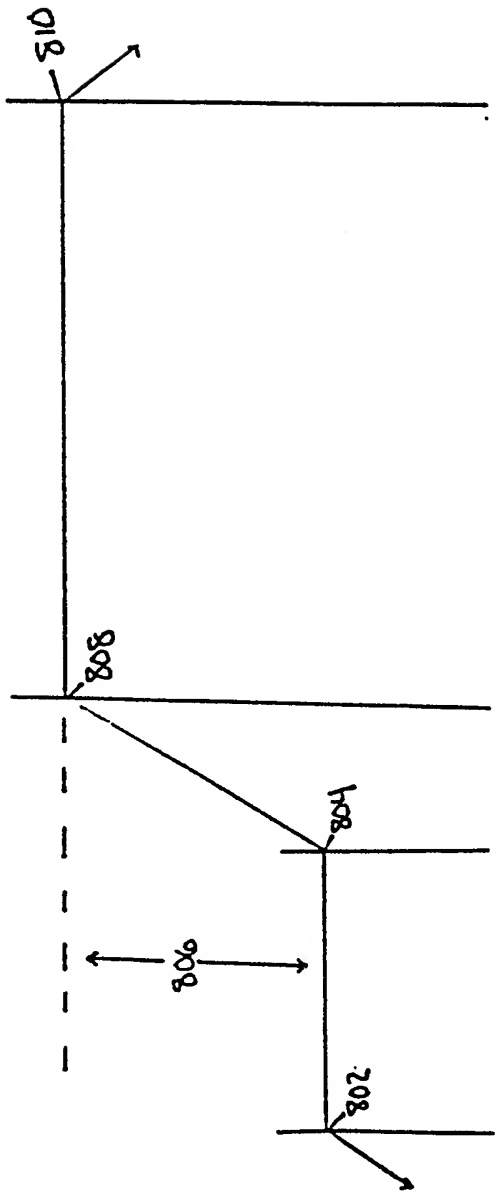


Fig. 7

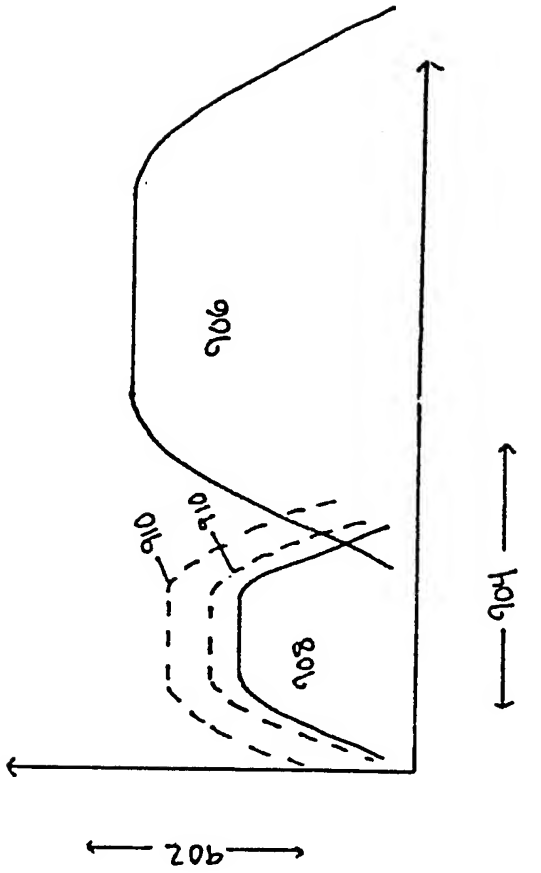
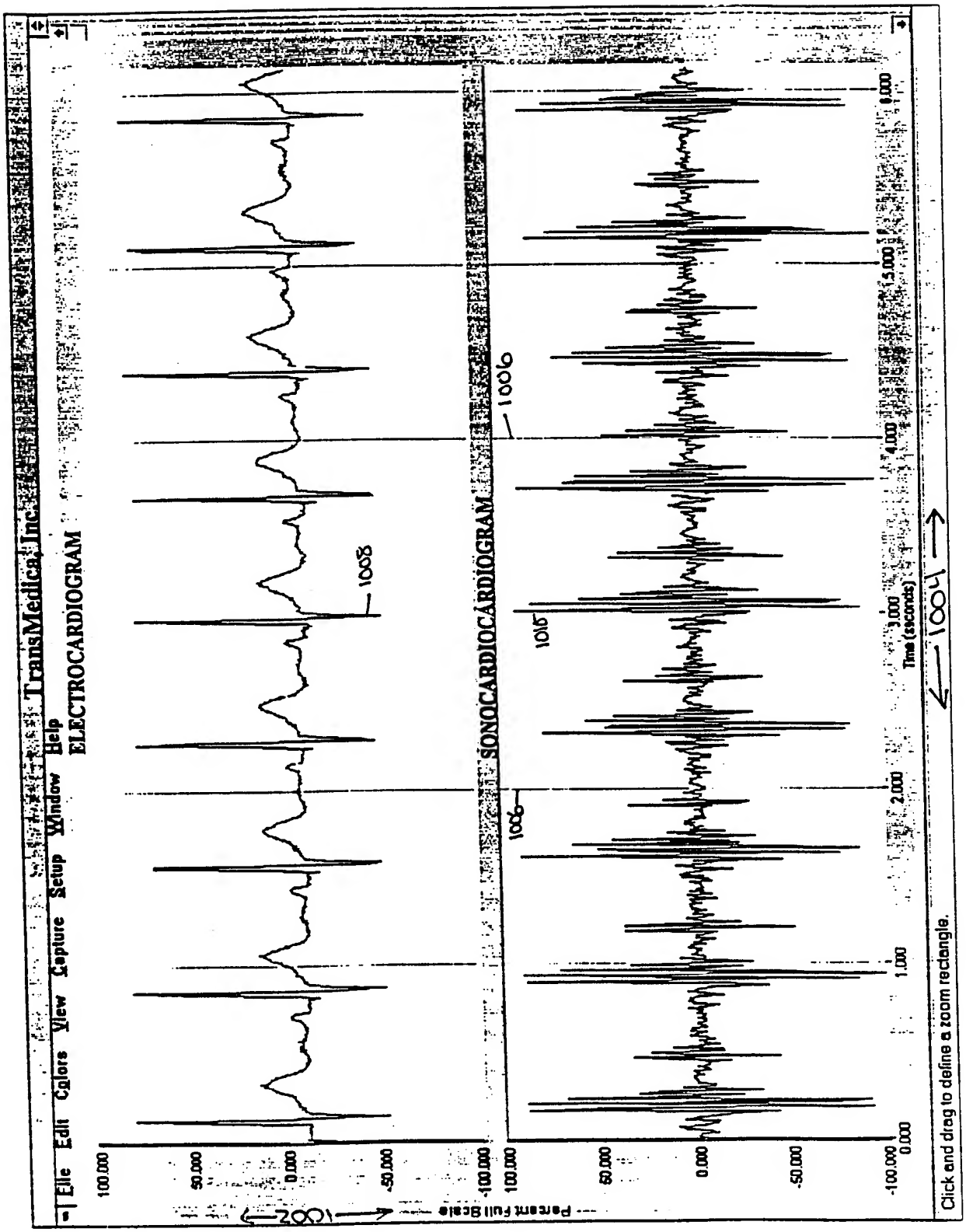


Fig. 8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Time (seconds)
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Fig. 9

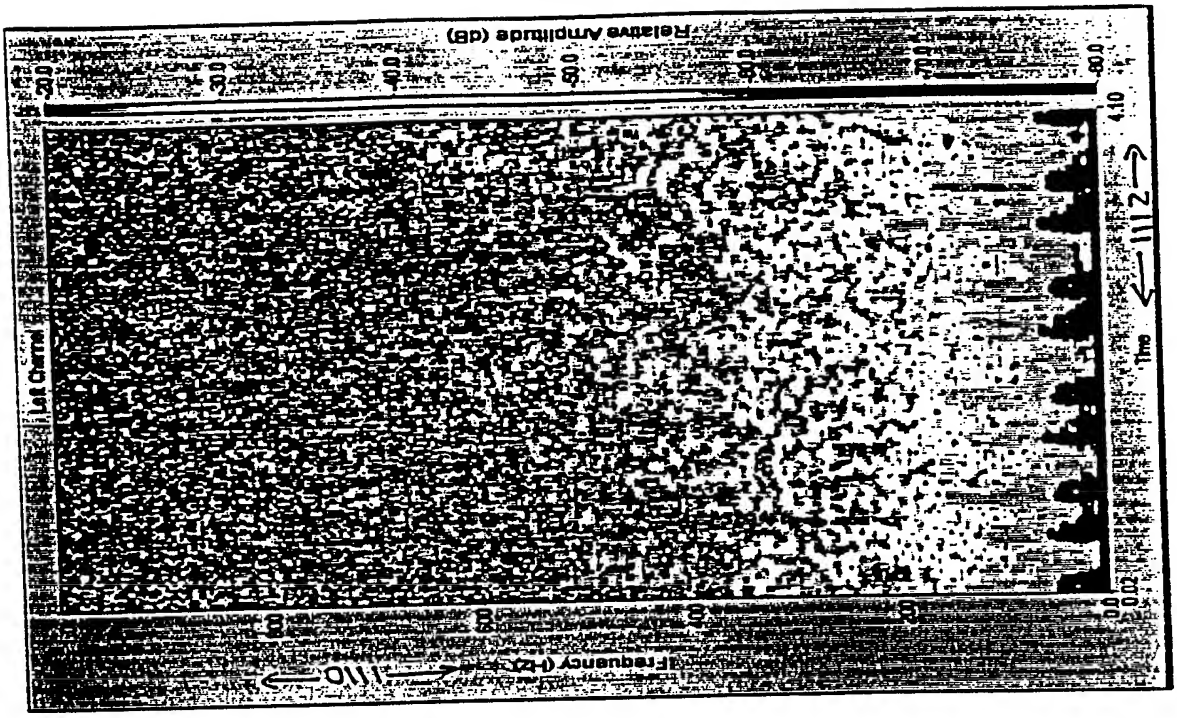


Fig. 10c

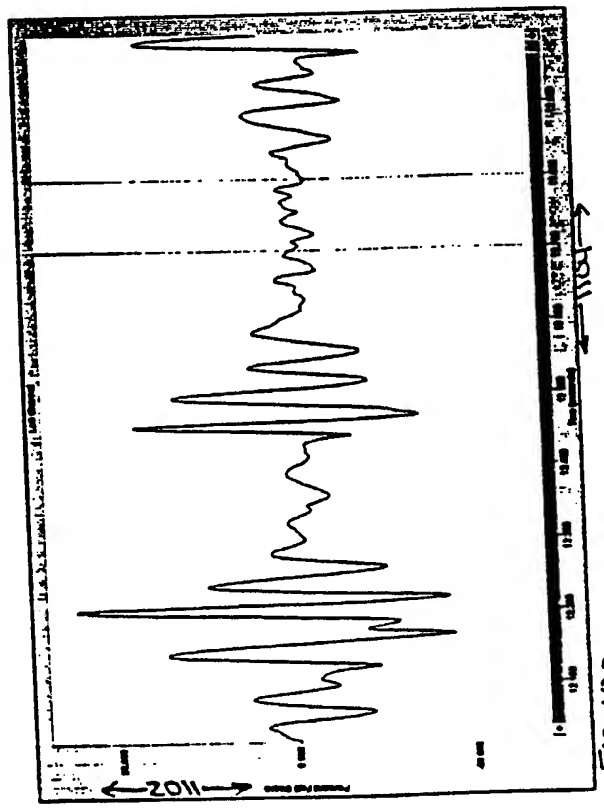


Fig. 10a

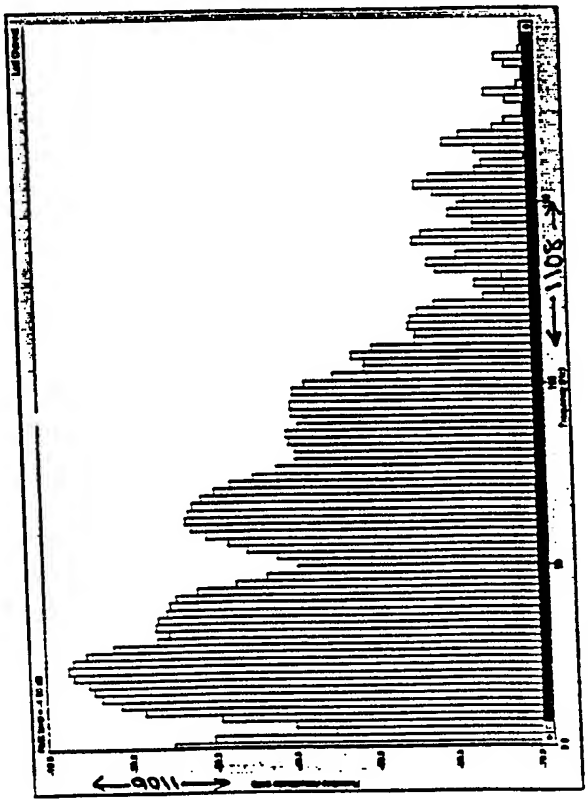
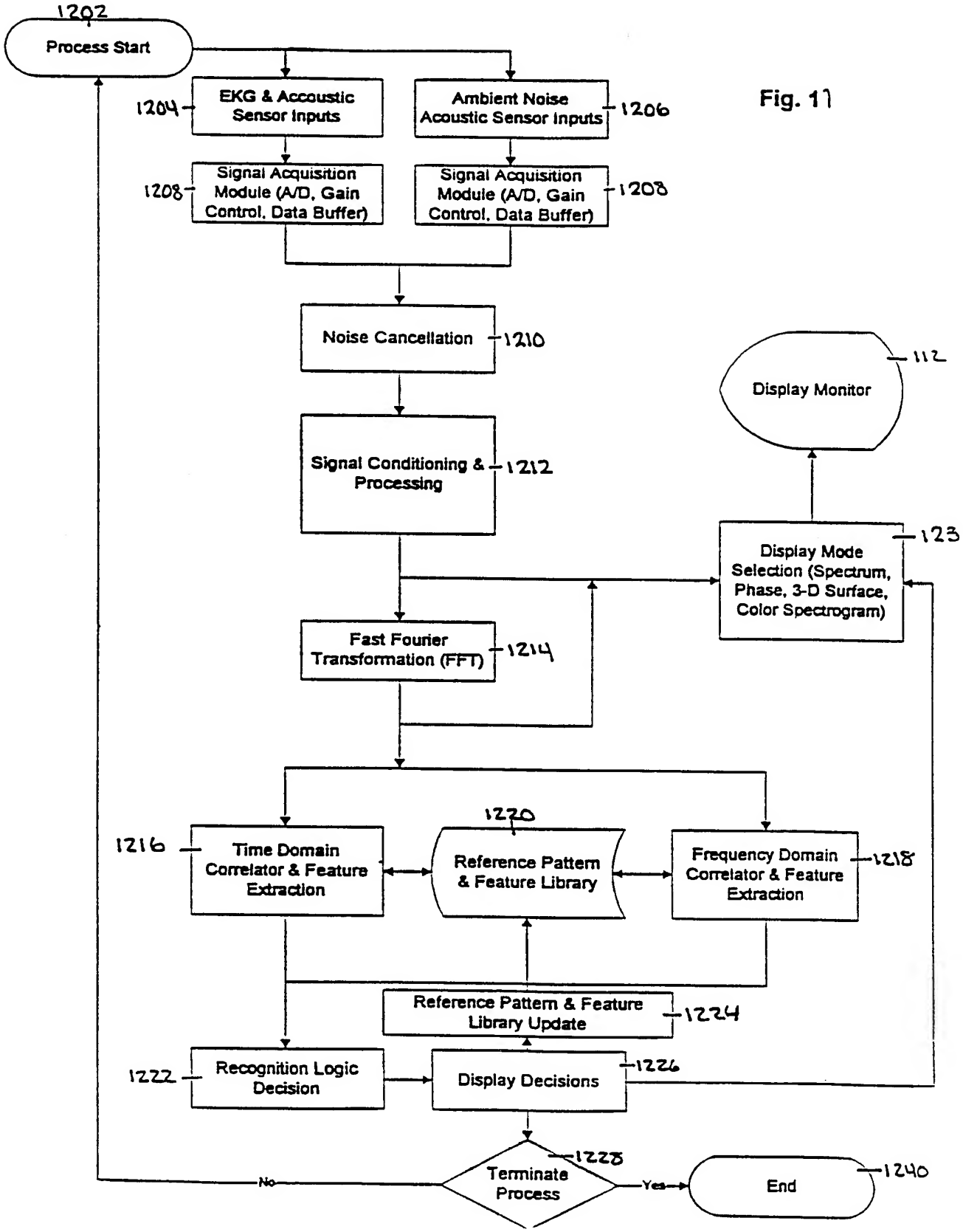


Fig. 10b


1202
Process Start
1204
EKG & Accoustic Sensor Inputs
Ambient Noise Acoustic Sensor Inputs
1206
1208
Signal Acquisition Module (A/D, Gain Control, Data Buffer)
Signal Acquisition Module (A/D, Gain Control, Data Buffer)
1208
Noise Cancellation
1210
112
Display Monitor
Signal Conditioning & Processing
1212
123
Display Mode Selection (Spectrum, Phase, 3-D Surface, Color Spectrogram)
Fast Fourier Transformation (FFT)
1214
1220
1216
Time Domain Correlator & Feature Extraction
Reference Pattern & Feature Library
Frequency Domain Correlator & Feature Extraction
1218
Reference Pattern & Feature Library Update
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1222
Recognition Logic Decision
Display Decisions
1226
1228
Terminate Process
No
Yes
End
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Fig. 11

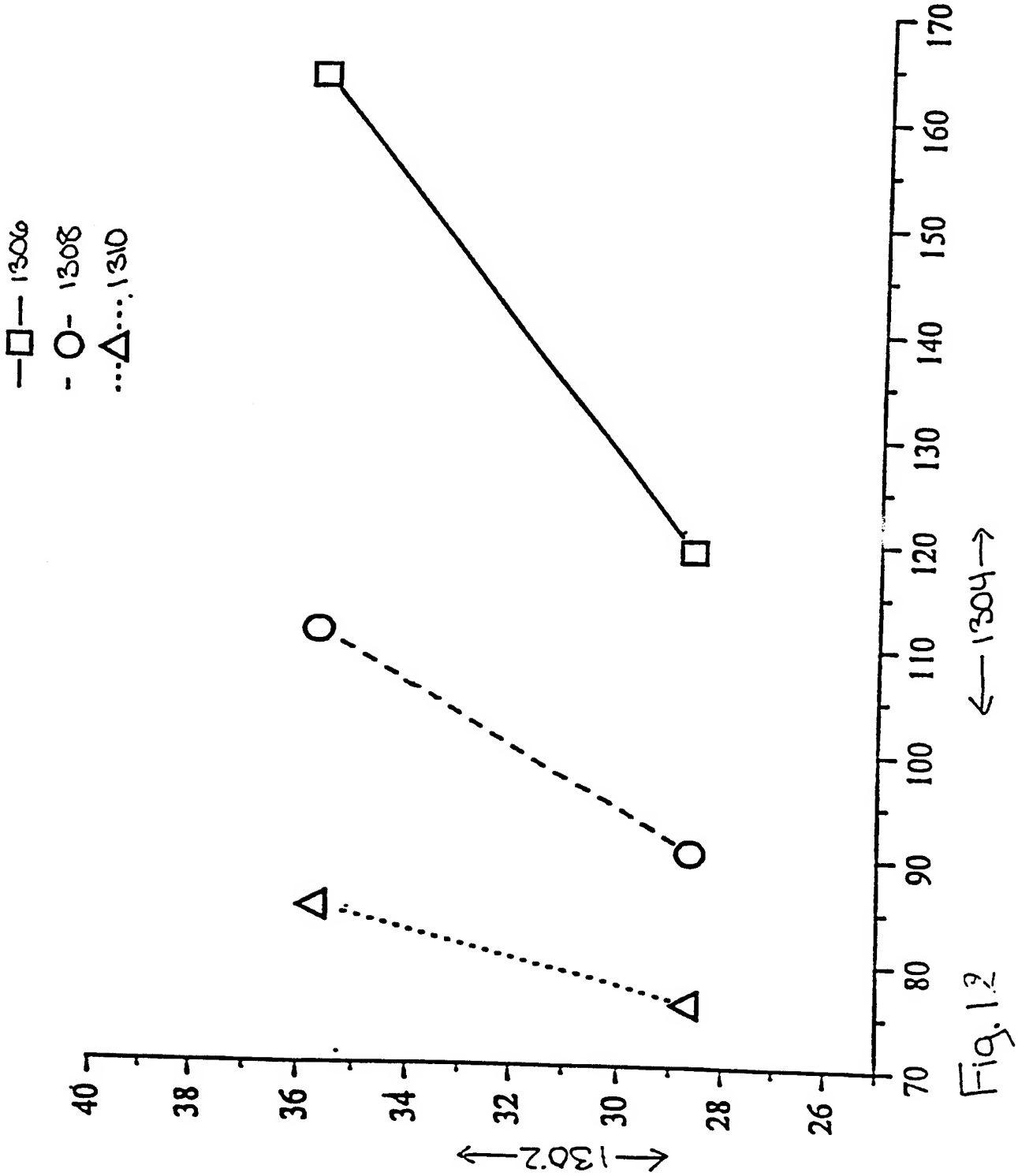
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Fig. 12

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 97/21917

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B7/04

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 020 110 A (W.J. KASPARI) 10 December 1980	1-4,7, 9-11,14, 25,26, 32, 34-37, 39, 43-45, 48, 50-52, 60-62, 65,69
A	see page 3, line 4 - line 37	6,47,55
A	see page 7, line 11 - page 9, line 18 see page 12, line 24 - page 17, line 17	57,58

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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1

Date of the actual completion of the international search	Date of mailing of the international search report
7 April 1998	17/04/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rieb, K.D.

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INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 97/21917

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category ³	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 467 775 A (T.F. CALLAHAN ET AL.) 21 November 1995	1-3,5, 10,14, 21, 25-28, 44-46, 48,51, 55,56,69
A	see column 4, line 41 - column 5, line 17	32-37
A	see column 6, line 5 - column 7, line 28	43,58
A	see column 8, line 5 - line 44 see column 11, line 56 - column 12, line 55	65,67

A	US 4 967 760 A (W.R. BENNETT, JR. ET AL.) 6 November 1990 cited in the application	1-5,14, 19,20
A	see column 1, line 25 - line 53	25-28
A	see column 4, line 1 - line 63	32-36,39
A	see column 9, line 9 - column 10, line 45	40,43-46
A	see column 10, line 66 - column 11, line 24 see column 13, line 64 - column 15, line 31	55,56, 65,67,69

A	US 5 025 809 A (K.H. JOHNSON ET AL.) 25 June 1991	1,14,25, 32,34-36
A	see column 6, line 19 - column 9, line 20	38-43

A	US 5 205 295 A (B. DEL MAR ET AL.) 27 April 1993	1,14, 16-20, 25,35
A	see column 9, line 46 - column 11, line 44	36,38-42

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/US 97/21917

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		WO 9008503 A	09-08-90
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US 5025809 A	25-06-91	NONE	
US 5205295 A	27-04-93	WO 9404075 A	03-03-94

CORRECTED VERSION*

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(30) Priority Data:
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(71)(72) Applicant and Inventor: MOHLER, Sailor [US/US]; 5410 Lightening View, Columbia, MD 21045 (US).

(74) Agent: ROBERTS, Jon, L.; Roberts & Brownell, L.L.C., Suite 212, 8381 Old Courthouse Road, Vienna, VA 22182 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

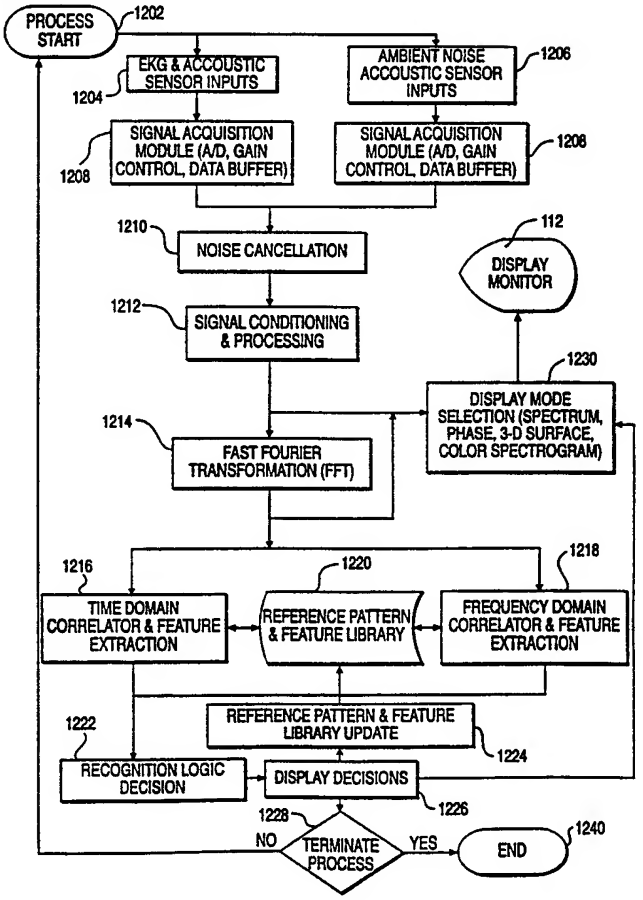
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT

(57) Abstract

An apparatus detection of the second heart sound acoustic signature associated with heart valve closure includes a sensor assembly (102) comprising a housing (302; 402), an electronic module (314; 422), a shock dampener (316; 432; 434), a mounting means, a transducer (320; 432; 434), an acoustic coupling (322; 436; 438) and a back cover. The sensor assembly (102) is connected to a data acquisition module (103) which in turn is connected to a signal processing means (104), a remote connection means (110) and a monitor (112). An improved acoustic coupling (322; 436; 438) is disclosed that provides low–loss acoustic transmission between the skin of the patient and the sensor assembly (102).



*(Referred to in PCT Gazette No. 41/1998, Section II)

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TITLE: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT

FIELD OF THE INVENTION

This invention relates generally to an apparatus, operation and method for measurement of blood pressure. In particular, this invention relates to an apparatus, operation and method for the detection, identification and characterization of sounds relating to either systemic or pulmonary blood pressure through the use of sonospectrography.

BACKGROUND OF THE INVENTION

Blood pressure is the force exerted by the blood against the inner walls of blood vessels. Blood pressure determination is an important diagnostic tool. The blood vessels that comprise the vascular system can be grouped into two main divisions, a systemic circuit and a pulmonary circuit. In the systemic circuit, high blood pressure may indicate the presence of arteriosclerosis or other vascular disease, while low blood pressure may indicate shock or blood loss. Detection and measurement of elevated pulmonary blood pressure is a key diagnostic indicator for a number of pulmonary diseases, such as: cystic fibrosis, pleuresy, lung pulmonary diseases, and pulmonary impedance. Early diagnosis of these diseases greatly assists in symptom mitigation and improved patient quality of life.

The systemic circuit includes the aorta and its branches that deliver oxygenated blood to all body tissues, as well as the companion system of veins returning blood to the right atrium. Freshly oxygenated blood received by the left atrium is forced into the systemic circuit by the contraction of the left ventricle. When the left ventricle contracts, the mitral valve closes, and the only exit is through the aortic valve into the aorta.

The peripheral nature of certain systemic circuit arteries in the body extremities allows for the traditional indirect measurement of the systolic and diastolic pressures with a sphygmomanometer blood pressure cuff. While this method is effective for many patients, use of the traditional blood pressure cuff on an extremity may be contraindicated for patients suffering from any number of problems including severe extremity trauma, or burns. In patients where use of the traditional blood pressure cuff is contraindicated, there is no reliable alternative method of

monitoring blood pressure. This is extremely important in trauma patients where prompt detection of blood pressure changes are needed to counteract the effects of shock or large blood loss.

The pulmonic circuit provides for blood circulation from the right ventricle through the pulmonary valve into the pulmonary artery. The pulmonary artery extends upward and posteriorly from the heart, dividing into right and left branches which serve the right and left lungs, respectively. Within the lungs the right and left branches of the pulmonary artery divide repeatedly giving rise to arterioles that continue into the capillary networks associated with the walls of the alveoli. Gas exchange occurs as the blood moves through these capillaries, so that when the blood enters the venules of the pulmonary circuit, it is well oxygenated and poor in carbon dioxide. The pulmonary venules merge forming small veins, which in turn converge forming larger veins. Four pulmonary veins return oxygenated blood to the left atrium, thereby completing the pulmonic circuit.

None of the arteries of the pulmonic system are located in extremities and therefore measurement of pulmonic system pressure with a blood pressure cuff is not possible.

At present, the only reliable method for measuring pulmonic system blood pressure is through use of an invasive blood pressure catheter that is inserted directly into the pulmonary artery. This diagnostic procedure has a substantial degree of risk and is expensive, its use is thus generally seen as an unjustified procedure in patients without other symptoms.

The physician may attempt to detect and differentiate the abnormal sounds that occur with elevated blood pressure using traditional auscultation. Closure of the aortic and pulmonary semilunar heart valves generate a sound component that is in the audio frequency range. As the systemic or pulmonic blood pressure increases, the frequency components of the related heart valve also increase. This increased frequency audio component is not present in a healthy patient. However, aural detection of this frequency increase is extremely difficult because the physician must determine the absolute frequency of the audio component of the heart valve of interest. Additionally, the sounds are very weak and heavily contaminated with noise from other patient heart sounds, other normal patient body sounds and external ambient noise in the room. Further, the audio component of the aortic and pulmonary semilunar heart valves are heavily attenuated as they pass through the patient's chest and chest wall.

A need exists for a non-invasive, low cost and reliable means for determining systemic

blood pressure in those situations where traditional means are contraindicated. A need also exists for a non-invasive, low cost and reliable means for determining pulmonary blood pressure.

DESCRIPTION OF RELATED ART

As mentioned, the sounds related to systemic and pulmonary heart pressure are difficult to discern. United States Patent No. 4,528,690 to Sedgwick; United States Patent No. 3,790,712 to Andries; and United States Patent No. 3,160,708 to Andries et al. disclose relatively simple electronic stethoscopes as methods for amplification of the sounds in an attempt to raise the sub-audible components into the audible range. However, simple amplification of the entire frequency spectrum, as disclosed, does not help in determining the absolute frequency of the heart valve sounds, or in detecting the subtle changes of this frequency that occur with changes in blood pressure.

To this end, United States Patent No. 4,594,731 to Lewkowicz and United States Patent No. 5,347,583 to Dieken et al. disclose various forms of selective filtering or signal processing on the audio signal in the electronic stethoscope. Lewkowicz discloses a means for shifting the entire detected spectrum of sounds upward while expanding the bandwidth so that they are more easily perceived by the listener. Dieken et al. discloses an electronic stethoscope having a greater volume of acoustic space and thereby improving low frequency response.

The electronic stethoscope provides a moderate improvement over conventional methods of auscultation. However, information remains in audio form only and is transient; the physician is unable to visualize the data and either freeze the display or focus on a particular element of the signal retrieved. To accommodate that deficiency, the technique of phonocardiography, which is the mechanical or electronic registration of heart sounds with graphic display, is used. United States Patent No. 5,218,969 to Bredesen et al.; United States Patent No. 5,213,108 to Bredesen et al.; United States Patent No. 5,012,815 to Bennett, Jr. et al.; United States Patent No. 4,967,760 to Bennett, Jr. et al.; United States Patent No. 4,991,581 to Andries; and United States Patent No. 4,679,570 to Lund et al. disclose phonocardiography with signal processing and visual/audio output. United States Patent No. 5,301,679 to Taylor; and United States Patent No. 4,792,145 to Eisenberg et al. disclose phonocardiography with signal processing and visual display.

The process of phonocardiography as commonly known in the art, acquires acoustic data through an air conduction microphone strapped to a patients chest, and provides the physician with a strip chart recording of this acoustic data. The strip chart is generally created at a rate of 100 mm/second. As this method is generally used, with the exception of the created strip chart, data is not stored. Thus, it is not possible to manipulate and/or process the data post acquisition. In addition, phonocardiography does not provide the sensitivity needed to monitor softer physiological sounds such as the closure of the semilunar valves and blood flow through the circulatory system.

As previously noted, one problem in traditional auscultation is ambient noise from the room in which the examination is occurring, which reduces the signal-to-noise ratio of the sounds of interest. United States Patent No. 4,672,977 to Kroll discloses a method for automatic lung sound cancellation and provides visual and audio output. United States Patent No. 5,309,922 to Schecter et al. discloses a method for cancellation of ambient noise to enhance respiratory sounds and provides visual and audio output. United States Patent No. 5,492,129 to Greenberger discloses a method for reducing general ambient noise and provides audio output.

United States Patent No. 5,036,857 to Semmlow et al. discloses a method of phonocardiography with piezoelectric transducer. Semmlow specifically recommends against Fast Fourier Transformation analysis of the phonocardiography data and relies on processing by other means. United States Patent No. 5,109,863 to Semmlow et al.; and United States Patent No. 5,035,247 issued to Heimann also disclose piezoelectric transducers.

United States Patent No. 5,002,060 to Nedivi, discloses both heart and respiratory sensors, with Fast Fourier Transformation analysis. In the technique disclosed by Nedivi the sensors are not physically attached to the patient. Thus the sensors are not capable of detecting the low intensity sound of the aortic and pulmonary semilunar heart valves.

Devices currently known in the art do not provide either a means of determining systemic blood pressure where use of a blood pressure cuff is contraindicated, or a low risk, non-invasive means of determining pulmonic blood pressure. Additionally, the related art does not provide the level of aural sensitivity needed to reliably detect the sounds of the aortic and pulmonary semilunar heart valves and determine the precise frequency of these sounds.

What is needed is a safe, sensitive and noninvasive means of measuring systemic and/or pulmonic blood pressure. This is accomplished through the present invention. Through the use

of sonospectrography, a procedure based on integral spectral analysis techniques, systemic pressure can be monitored in conditions where traditional auscultation is contraindicated. Additionally, sonospectrography can be used to monitor pulmonic pressure in an inexpensive, noninvasive and low risk manner, allowing for the early detection of conditions such as cystic fibrosis, pleuresy, lung pulmonary diseases and pulmonary impedance. Sonospectrography is defined as the separation and arrangement of the frequency components of acoustic signals in terms of energy or time.

Further embodiments of the present invention provide a means of detecting physiological sounds, such as sounds emitted by the heart and other body organs as well as sounds related to the flow of blood through the circulatory system. Analysis of these sounds can be used to determine systemic and pulmonary blood pressure, monitor anesthesiology, determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic decrepitation, phlebitis, venous thrombosis, intravascular blood clotting and carotid artery disease.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide an apparatus, operation and method for the detection and analysis of physiological sounds, such as sounds emitted by the heart and other body organs as well as sounds related to the flow of blood through the circulatory system.

It is a further object of the present invention to provide an apparatus, operation and method to be used to determine systemic and pulmonary blood pressure, monitor anesthesiology, determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic decrepitation, phlebitis, venous thrombosis, intravascular clotting and carotid artery disease.

It is a further object of the present invention to provide this apparatus, operation and method through the use of sonospectrography.

It is a further object of the present invention to provide this apparatus, operation and method through a synchronized and coordinated combination of sonospectrography and electrocardiogram signals.

It is a further object of the present invention to provide this apparatus, operation and method through visual display means that provide insight to the subtle characteristics of the acoustic signature.

It is a further object of the present invention to provide this apparatus, operation and method through selective time and frequency windowing of the acoustic signals.

It is a further object of the present invention to provide this apparatus, operation and method through real-time signal processing or recorded-signal post processing.

It is a further object of the present invention to provide this apparatus, operation and method through use of single or multiple transducers.

It is a further object of the present invention to provide this apparatus, operation and method through a computer assisted search algorithm to identify optimal placement of the transducer(s) on the patient's chest wall.

It is a further object of the present invention to provide this apparatus, operation and method in office environments with moderate to high ambient noise levels, through adaptive noise cancellation techniques.

It is a further object of the present invention to provide this apparatus, operation and method in a form that provides for dynamic template building to facilitate disease detection and identification.

It is a further object of the present invention to provide this apparatus, operation and method through neural network techniques.

It is a further object of the present invention to provide an acoustic coupling that minimizes signal loss between the subject-detector interface and allows for the detection of sounds heretofore undetectable in a normal room environment.

It is a further object of the present invention to extend the ability of clinicians to analyze sounds which are lower in amplitude than those detectable by the unaided ear.

It is a further object of the present invention to extend the ability of clinicians to analyze sounds which are lower in frequency than those detectable by typical auscultation techniques.

It is a further object of the present invention to increase detection of a specified frequency range through the use of a tailored bandpass amplifier.

It is a further object of the present invention to provide a means for data storage, data manipulation and data transmission.

It is a further object of the present invention to provide this apparatus, operation and method through advanced processing of acoustic signatures in the time and frequency domain to isolate and display the sound components associated with pulmonary and/or aortic heart valve closure.

It is a further object of the present invention to provide an apparatus, operation and method that is suitable for routine physical examination screening and early diagnosis of elevated pulmonic blood pressure thereby providing an opportunity for early intervention to enhance the patient's productive life.

It is a further object of the present invention to provide an apparatus, operation and method that is suitable for monitoring of systemic blood pressure in patients where use of a traditional blood pressure cuff is contraindicated.

These and other objects of the present invention will become obvious to those skilled in the art upon review of the following disclosure.

An apparatus for determining blood pressure in accordance with the present invention includes a sensor assembly comprising a housing, an electronic module, a shock dampener, a mounting means, a piezoelectric transducer, an acoustic coupling and a back cover. The sensor assembly is connected to a data acquisition module which in turn is connected to a signal processing means. The signal processing means is connected to an electronic storage means, a hard copy reproduction means, a remote connection means and a monitor. In an alternative embodiment of the invention a plurality of sensor assemblies are connected to the data acquisition module. In another alternative embodiment of the invention a means for determining an electrocardiogram is connected to the signal processing means. In yet another alternative embodiment of the invention, data acquisition module is connected to high-fidelity earphones.

The operation for determining blood pressure in accordance with the present invention includes:

1) performing start-up procedures;
2) acquiring physiologic signals;
3) acquiring ambient or background signals;
4) processing and subtracting ambient signals from physiologic signals;
5) conditioning and processing resultant data;
6) subjecting the conditioned and processed data to Fast Fourier Transformation;

7) passing the time domain components of the data through a time domain correlator and feature extraction process;

8) passing the frequency domain components of the data through a frequency domain correlator and feature extraction process;

9) comparing the time domain output and the frequency domain output to a reference pattern and feature library;

10) determining whether the time domain output and frequency domain output match known disease modalities;

11) determining whether a disease modality is indicated;

12) updating the reference pattern and feature library; and

13) providing the information regarding the disease modality to the physician so that a treatment regimen may commence.

The method for determining blood pressure in accordance with the present invention includes monitoring the sounds of the aortic and/or the pulmonary semilunar valves. Where one wishes to determine systemic pressure, the aortic semilunar valve is monitored. This is done by placing the acoustic coupling of the sensor assembly adjacent to the patient's skin at the traditional auscultation point for the aortic valve. Where one wishes to monitor pulmonary pressure, the pulmonary semilunar valve is monitored. This is done by placing the acoustic coupling of the sensor assembly in contact with the patient's skin at the traditional auscultation point for the pulmonic valve. Detected signals are manipulated in the same fashion noted in the "operation" of the present invention. The signals may be viewed and analyzed by medical personnel at any number of points during this data manipulation process to allow for the implementation of a treatment regimen. Where the sound emitted by either semilunar valve is of a higher than normal frequency, this is indicative of increased blood pressure in the corresponding circuit; that is, an increased frequency emitted by the aortic semilunar valve is indicative of higher than normal systemic blood pressure, while an increased frequency being emitted by the pulmonary semilunar valve is indicative of higher than normal pulmonary blood pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic representation of the overall architecture and user interface of the present invention.

Figure 2a depicts an exploded, oblique view of the sensor assembly.

Figure 2b depicts an exploded, side view of the sensor assembly.

Figure 3 depicts an exploded, oblique view of an alternative embodiment of the sensor assembly.

Figure 4 depicts a circuit diagram of the electronic module, data cable and data acquisition module.

Figure 5 depicts a circuit diagram of greater detail, comprising the electronic module, data cable and data acquisition module.

Figure 6 depicts a circuit diagram of still greater detail, comprising the electronic module, data cable and data acquisition module.

Figure 7 depicts the frequency response of a tailored bandpass amplifier.

Figure 8 illustrates the simultaneous display of ECG and acoustic signal data.

Figure 9a illustrates an acoustic amplitude vs. time display mode.

Figure 9b illustrates a relative amplitude vs. frequency display mode.

Figure 9c illustrates a frequency vs. time display mode.

Figure 10 is a flow chart illustrating the operation of the present invention.

Figure 11 graphs the relationship of second heart sound frequency vs. blood pressure.

DETAILED DESCRIPTION

The present invention provides an apparatus, operation and method to passively and non-invasively measure systemic and pulmonic blood pressure through detection, identification and characterization of the acoustic signature associated with heart valve closure.

APPARATUS

Referring to Figure 1, the overall architecture of the present invention is described. Patient physiologic signals, such as acoustic vibrations or electrical impulses, are detected by sensor assembly **102**. In an alternative embodiment a plurality of sensor assemblies can be used

to either simultaneously obtain signals from various locations of the body or to simultaneously obtain signals from both the patient and the environment. Sensor assembly **102** is connected to data acquisition means **103**.

Data acquisition means **103** comprises preamplifier **114**, audio amplifier **116**, and analog-to-digital converter **118**. Preamplifier **114** electronically isolates the transducer, detects the electronic signals, and sends them to audio amplifier **116** and to analog-to-digital converter **118**. Audio amplifier **116** drives one or more sets of high-fidelity earphones **120**. Analog-to-digital converter **118** samples the analog signal and converts it to a binary number for each time sample. Data acquisition means **103** is connected to signal processing means **104**.

Signal processing means **104** is a general-purpose microprocessor. Signal processing means **104**, also has means for video display of information, such as monitor **112**. Signal processing means **104** is connected to electronic data storage means **106**, operator input means **107**, hard copy reproduction means **108** and remote connection means **110**.

Various types of electronic data storage are known to those skilled in the art. In alternative embodiments electronic data storage means **106** comprises: internal hard disk drive, external hard disk drive, floppy disks, digital audio tape, magneto-optical storage or CD ROM. Likewise, various types of operator input means are known to those skilled in the art. In alternative embodiments operator input means **107** comprises: keyboard, mouse, voice detector or other means. Hard copy reproduction means **108** provides copies of images displayed on monitor **112** for purposes such as maintaining medical records, assisting consultations, and assisting data processing and review. Remote connection means **110** is a modem. In alternative embodiments, the system of the present invention may be directly linked to a network via a network interface card or other suitable means. Thus a modem may not always be necessary.

In an alternative sensor assembly embodiment, sensor assembly **102** can detect both physiologic and background signals. In another alternative sensor assembly embodiment, one side of sensor assembly **102** comprises an audio transducer which is in contact with the skin while a second audio transducer on the opposite side faces away from the patient. This second transducer is designed to acquire ambient sounds in synchronism with the sounds reaching the transducer in contact with the patient's skin to reject common mode signals reaching both transducers. By adding the environmental signals out of phase with the signals acquired from the

patient, the sounds in common to both transducers are effectively canceled. In yet another alternative sensor assembly embodiment the target frequency range for data acquisition is about 200 to 2000 Hz. In another alternative sensor assembly embodiment, the target frequency range for signal acquisition is about 400 hertz.

In an alternative preamplifier embodiment, preamplifier **114** demonstrates low-noise data acquisition and proper impedance matching.

In an alternative analog-to-digital converter embodiment analog-to-digital converter **118** has a sample rate about 4 to 48 Khz. In yet another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a sample rate of about 44 Khz. In another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a resolution of about 16 bits. In yet another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a linearity about ± 0.005 percent of full scale. In another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a sample length of about one to sixty seconds. In yet another alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has an operator selectable sample length.

In an alternative earphones embodiment, earphones **120** have separate volume controls.

In an alternative signal processing means embodiment, signal processing means **104** is a computer with a central processing unit. In another alternative signal processing means embodiment, signal processing means **104** is an IBM compatible personal computer using an INTEL processor (386, 486, Pentium), having a minimum of 8 MB RAM memory and a minimum hard disk size of 500 MB. In yet another alternative signal processing means embodiment, signal processing means **104** is a Macintosh PowerPC.

In an alternative monitor embodiment, monitor **112** has a minimum display size of 600 X 400 pixels and a minimum monitor **112** display depth of eight bits. In yet another alternative monitor embodiment, monitor **112** is a high resolution EGA or VGA color display monitor.

In an alternative signal processing means embodiment, signal processing means **104** comprises a sound card. In another alternative signal processing means embodiment, the sound card comprises a "Tahiti" multiple channel computer sound card manufactured by Turtle Beach, although sound cards such as the Pro Audio 1b (Media Vision) can also be used.

In an alternative hard copy reproduction means embodiment, hard copy reproduction

means **108**, is a printer. In another alternative hard copy reproduction means embodiment, hard copy reproduction means **108** is a printer capable of generating a variety of different graphic displays. In yet another alternative hard copy reproduction means embodiment, hard copy reproduction means **108** is a laser printer.

In an alternative remote connection means embodiment, remote connection means **110** is an internal or external, high speed modem. In another alternative remote connection means embodiment, remote connection means **110** has a speed of at least 14.4 kilobytes per second.

Referring to Figure 2a, an oblique view of an embodiment of sensor assembly **102** is shown. Figure 2b depicts a side view of an embodiment of sensor assembly **102**. Housing **302** comprises a sound deadening material having sufficient mass to dampen high frequency ambient disturbances and hold the sensor assembly in contact with the patient through gravity. Housing **302** has housing front **304** and housing back **306**. Rim **308** is located on the periphery of housing front **304**. First indentation **310** runs parallel and adjacent to the inside of rim **308**. Second indentation **312** runs parallel and adjacent to the inside of first indentation **310**. Bore **312** is approximately centrally located within second indentation **312** and is shaped and sized in conformity to the shape and size of electronic module **314**. Electronic module **314** nests within bore **312** of housing **302**. As will be further discussed, signal detection and processing circuitry are incorporated within electronic module **314**.

Shock dampener **316** is positioned adjacent to first indentation **310**. Mounting means **318** is positioned adjacent to shock dampener **316**. Transducer **320** is positioned within mounting means **318**. Transducer **320** converts detected signals into electronic signals. Acoustic coupling **322** is positioned adjacent to transducer **320**. Acoustic coupling **322** serves to dilinearize excitation response and reduce dynamic range.

Once assembled, housing **302** is closed to the ambient environment with back cover **324**. Sensor assembly **102** comprising all the individual sensor elements, is assembled and sealed to form a single complete unit.

In an alternative housing embodiment, housing **302** is composed of nickel plated aluminum, but can be any material having sufficient mass to dampen high frequency ambient disturbances and hold the sensor in contact with the patient through gravity.

In an alternative sensor assembly embodiment, when electronic module **314** nests within

bore **312** of housing **302**, top **316** of electronic module **314** is flush with second indentation **312**.

In an alternative shock dampener embodiment shock dampener **316** is an "O" ring.

In an alternative mounting means embodiment, mounting means **318** is a plastic mounting ring.

In an alternative transducer embodiment, transducer **320** is a piezoelectric disk. In another alternative transducer embodiment, transducer **320** has a high impedance. In yet another alternative transducer embodiment, transducer **320** has an impedance of about 470 Kohms. In another alternative transducer embodiment, transducer **320** has high efficiency as compared with conventional electromagnet type speakers. In yet another alternative transducer embodiment, transducer **320** is ultra thin and lightweight. In another alternative transducer embodiment, transducer **320** has a frequency range of about 500 - 20,000 Hz. In yet another alternative transducer embodiment, transducer **320** has a capacitance at 120 Hz of about 60 ± 30 % nF. In another alternative transducer embodiment, transducer **320** current leakage is limited to about one micro ampere.

In an alternative acoustic coupling embodiment, acoustic coupling **322** is impedance matched, and serves to provide a low-loss acoustic transmission coupling between the skin of the patient and transducer **320**, thereby minimizing signal loss across the subject-detector interface. In another alternative acoustic coupling embodiment, acoustic coupling **322** is a parametric acoustic transconductor. In yet another acoustic coupling embodiment, acoustic coupling **322** has a high conduction coefficient. In another alternative acoustic coupling embodiment, acoustic coupling **322** is made of latex foam. In yet another alternative acoustic coupling embodiment, acoustic coupling **322** is logarithmically attenuated, having low transmission at low frequencies and high transmission at high frequencies.

Referring to Figure 3 an oblique exploded view of an alternative embodiment of sensor assembly **102** is shown. Housing **402** comprises a sound deadening material having sufficient mass to dampen high frequency ambient disturbances and hold the sensor assembly in contact with the patient through gravity. Housing **402** has housing front **404** and housing back **406**. First rim **408** is located on the periphery of housing front **404**. Second rim **410** is located on the periphery of housing back **406**. First indentation **412** runs parallel and adjacent to the inside of first rim **408**. Second indentation **414** runs parallel and adjacent to the inside of first indentation

412. Third indentation **416** runs parallel and adjacent to the inside of second rim **410**. Fourth indentation **418** runs parallel and adjacent to the inside of third indentation **416**. First bore **420** is approximately centrally located within second indentation **414** and is shaped and sized in conformity to the shape and size of first electronic module **422**. Second bore **440** is approximately centrally located within fourth indentation **418** and is shaped and sized in conformity to the shape and size of second electronic module **442**. First electronic module **422** nests within first bore **420** of housing **402**. Second electronic module **442** nests within second bore **440** of housing **402**. As will be further discussed, signal detection and processing circuitry are incorporated within first and second electronic module **422, 442**.

First shock dampener **424** is positioned adjacent to first indentation **412**. Second shock dampener **426** is positioned adjacent to third indentation **416**. First mounting means **428** is positioned adjacent to first shock dampener **424**. Second mounting means **430** is positioned adjacent to second shock dampener **426**. First transducer **432** is positioned within first mounting means **428**. Second transducer **434** is positioned within second mounting means **430**. First transducer **432**, converts detected physiologic signals into electronic signals. Second transducer **434**, converts detected environmental or background signals into electronic signals. First acoustic coupling **436** is positioned adjacent to first transducer **432**. Second acoustic coupling **438** is positioned adjacent to second transducer **434**. First and second acoustic coupling **436, 438** serve to dilinearize excitation response and reduce dynamic range.

In an alternative housing embodiment, housing **402** is composed of nickel plated aluminum.

In an alternative shock dampener embodiment, first and second shock dampener **424, 426** is an "O" ring.

In an alternative mounting means embodiment, first and second mounting means **428, 430** is a plastic mounting ring.

In an alternative transducer embodiment, first and second transducer **432, 434** is a piezoelectric disk. In another alternative transducer embodiment, first and second transducer **432, 434** has a high impedance. In yet another alternative transducer embodiment, first and second transducer **432, 434** has an impedance of about 470 Kohms. In another alternative transducer embodiment, first and second transducer **434, 434** has high efficiency as compared

with conventional electromagnet type speakers. In yet another alternative transducer embodiment, first and second transducer **432, 434** is ultra thin and lightweight. In another alternative transducer embodiment, first and second transducer **432, 434** has a frequency range of about 5 - 2,000 Hz. In yet another alternative transducer embodiment, first and second transducer **432, 434** has a capacitance at 120 Hz of about 60 ± 30 % nF. In another alternative transducer embodiment, first and second transducer **432, 434** current leakage is limited to about one micro ampere.

In an alternative acoustic coupling embodiment, first and second acoustic coupling **436, 438,** is impedance matched, and serves to provide a low-loss acoustic transmission coupling between the skin of the patient and first transducer **432**, thereby minimizing signal loss across the subject-detector interface. In another alternative acoustic coupling embodiment, first and second acoustic coupling **436, 438** is a parametric acoustic transconductor. In yet another acoustic coupling embodiment, first and second acoustic coupling **436, 438** has a high conduction coefficient. In another alternative acoustic coupling embodiment, first and second acoustic coupling **436, 438** is made of latex foam. In yet another alternative acoustic coupling embodiment, acoustic coupling **322** is logarithmically attenuated, having low transmission at low frequencies and high transmission at high frequencies.

Referring to Figure 4, electronic module **314**, transducer **320**, data cable **502**, and data acquisition module **504** of the present invention are shown in schematic form. In combination, first resistor **506**, semiconductor device **508**, second resistor **510**, and first capacitor **512** comprise electronic module **314**. Electronic module **314** performs functions such as signal amplification, and filtering. Transducer **320** is connected in parallel with first resistor **506**, second resistor **510**, first capacitor **512**, and semiconductor **508**. Semiconductor **508** serves to modulate current. First capacitor **512** provides gain and source decoupling for semiconductor **508**.

In an alternative first resistor embodiment, first resistor **506** provides a matching load to transducer **320**. In another alternative first resistor embodiment first resistor **506** has a resistance of 470 Kohms.

In an alternative second resistor embodiment, second resistor **510** is about 10 Kohms.

In an alternative semiconductor embodiment, semiconductor **508** is field effect transistor.

In another alternative semiconductor embodiment, semiconductor **508** is a field effect transistor with an N-type base.

In an alternative first capacitor embodiment, first capacitor **512** is 60 microfarads and is connected to ground.

Figure 5 depicts a circuit diagram of the electronic module, data cable and data acquisition module in greater detail. The circuit comprises electronic module **314**, transducer **320**, data cable **502**, and data acquisition module **504**. Data cable **502** couples electronic module **314** to data acquisition module **504**. Data acquisition module **504** comprises an amplifier. As depicted in Fig. 5, highpass filter **606** is followed by lowpass filter **608** having a DC injection point. The amount of DC injection is made variable by value selection of variable resistor **610**. In an alternative value selection embodiment, value selection is determined by the practitioner. In yet another alternative value selection embodiment, value selection is determined automatically by the signal processing means in conformity with predetermined parameters.

In an alternative data cable embodiment, data cable **502** is twisted pair **602**, wherein two insulated wires are twisted forming a flexible line without the use of spacers. In another alternative data cable embodiment, data cable **502** is shielded pair **604**, wherein two parallel conductors are separated from each other and surrounded by a solid dielectric. In this alternative embodiment, the conductors are contained within a copper-braid tubing that acts as a shield. The assembly is covered with a rubber or flexible composition coating to protect the line against moisture and friction. There are two advantages of this alternative embodiment: (1) the capacitance between each conductor and ground is uniform along the entire length of the line; and (2) the wires are shielded against pickup of stray electric fields. In yet another alternative embodiment shielded pair **604** data cable **502** is connected to sensor housing **610** and to ground as a means for reducing electrical noise and increasing patient safety.

In an alternative data acquisition module embodiment, data acquisition module **504** has a low frequency response from about 10 Hz to a crossover point at 100 Hz, rising to a level 20 dB higher from about 600 Hz to 2 KHZ, then declining steadily beyond that point. In another alternative data acquisition module embodiment, data acquisition module **504** comprises a voltage gain, variable from zero to fifty, allowing recovery of low-level sounds from 600 to about 2000 Hz while preserving the ability to measure low-frequency signals having a relatively high

amplitude, without amplifier saturation.

In an alternative highpass filter embodiment, highpass filter **606** has a gain of about 7, and lowpass filter **608** drives an output amplifier with a gain of about 7. In another alternative highpass filter embodiment the overall voltage gain available with the gain potentiometer at maximum will be about 50. An advantage of this alternative embodiment is the ability to reject a narrow range of frequencies in a notch caused by the phase delay in the components of highpass filter **606**. In an alternative highpass filter embodiment this notch is set at 100 Hz. In another alternative highpass filter embodiment this notch is set at about 50 - 60 Hz, thereby providing a measure of hum rejection

Figure 6 depicts a circuit diagram of the electronic module, data cable and data acquisition module in greater detail. The circuit comprises electronic module **314**, transducer **320**, data cable **502**, and data acquisition module **504**. Three stage resistor/capacitor network **702** gives a total of about 180 degrees of phase shift at a design frequency of about 100 Hz that is related to the combined resistor/capacitor time constants of the network. Field effect transistor **508** input is AC-coupled to the four-pole lowpass filter **608** formed by a single 747-type operational amplifier pair.

Figure 7 depicts an idealized shape of an amplifier having low-frequency response from first point **802** to crossover point **804** and having higher frequency response of predetermined level **806**, from second point **808** to third point **810**. In an alternative embodiment, first point **802** is about 10 Hz, crossover point **804** is about 100 Hz, predetermined level **806** is about 20 dB, second point **808** is about 600 Hz and third point **810** is about 2 Khz. In yet another alternative embodiment, crossover point **804** is about 60 Hz.

Figure 8 further depicts the response of the tailored bandpass amplifier, plotting amplitude **902** vs. frequency **904** of basic heart sounds **906** and sounds of interest **908**. In alternative embodiments, the response of sounds of interest **908** may be set at varying levels **910**.

Figure 9 depicts the simultaneous display of electrocardiogram and sonospectrography data. In the simultaneous display mode, the present invention provides for plotting electrocardiogram data and sonospectrography data as a function of intensity **1002** and time **1004**, with digital markers **1006** to allow the visual correlation of points of signal activity that may be common to both signals. As an example, the electrocardiogram pulse at **1008** can be

visually correlated with a select part of the acoustic signal **1010** and differentially measured to within 23 millionths of a second. This allows an operator who may be less familiar with acoustic signatures to correlate the electrocardiogram signal, which may be well understood, with the acoustic signal.

Referring to Figures 10a, 10b, and 10c, the display methodology of the present invention is shown. The present invention provides a means to simultaneously display the signal of interest in a variety of different forms. In Figure 10a, the signal of interest of the present invention is presented as a simple time series, with acoustic amplitude **1102** on the vertical scale and time **1104** on the horizontal scale. In Figure 10b, the signal of interest of the present invention is presented as a time and frequency display, with relative amplitude **1106** of each slice of the frequency spectrum on the vertical scale and frequency spectrum **1108** on the horizontal display. In Figure 10c, the signal of interest of the present invention is presented with frequency **1110** on the vertical axis, time **1112** on the horizontal axis, and relative amplitude plotted in different color hues (not shown) and/or grey scale intensity.

Having thus described the basic concept of the apparatus of the invention, it will be readily apparent to those skilled in the art that the foregoing detailed disclosure is intended to be presented by way of example only, and is not limiting. Various alterations, improvements and modifications will occur and are intended to those skilled in the art, but are not expressly stated herein. For example, while cardiovascular monitoring is a key aspect of the invention, the techniques described herein are equally applicable to the monitoring of other body organs and regions of the body of both humans and animals and thus may also find utility in the veterinary sciences. These modifications, alterations and improvements are intended to be suggested hereby, and are within the spirit and scope of the invention.

OPERATION

Figure 11 depicts the operation of the apparatus of the present invention with associated hardware and software. At step **1202**, start-up procedures are performed such as initialization, calibration, sensor selection, patient parameter input, and buffer clearing, among others. Upon completion of these start-up procedures steps **1204** and **1206** are initiated. At step **1204**, sensor **102** provides patient physiologic signals for signal processing. In an alternative embodiment,

sensor **102** can include electrocardiogram sensors and acoustic sensors. At step **1206** acoustic sensors are used to detect background or ambient noise.

Next, at step **1208**, the detected signals are passed to individual data acquisition modules which contain means for signal filtering, impedance matching, amplification, and buffering. These functions are performed by the components of the circuitry illustrated in Figs. 4-6.

At step **1210**, the signals from the ambient noise acoustic sensor acquired in step **1206**, are processed and subtracted from the signals from the desired sensor of step **1204** in a noise cancellation process to reduce the effect of ambient noise from the patient's environment.

At step **1212**, the signal undergoes additional signal conditioning and processing. The purpose of this conditioning step is to convert the analog signal to digital, provide adjustable decimation with a sampling rate suitable to avoid biasing, provide adjustable smoothing, averaging and peak holding. In an alternative embodiment the signal conditioning and processing of step **1212** is performed by a sound card which typically has the following capabilities: (1) a sample rate selectable from about 4 K to 44 K; (2) a sample size of about 16 bits; (3) capable of analog to digital conversion; (4) capable of digital to analog conversion; and (5) possesses IBM computer bus compatibility such as ISA, EISA, PCI, etc. In yet another alternative embodiment the sound card used comprises a "Tahiti" multiple channel Sound Card manufactured by Turtle Beach. Step **1230** allows for the intermediate output and display of the desired signal following the signal conditioning and processing of step **1212**. The display is accomplished by selection of a desired display mode and subsequent display on the monitor **112**. The output of step **1212** is of a time series and is suitable for display selection as in Figure 10a.

At step **1214**, the digitized and conditioned data is subjected to a sliding fast Fourier transformation. The output of step **1214** is of time and frequency and is suitable for display selection according to Figures 10b or 10c.

At step **1216**, time domain components of the data passes through a time domain correlator and feature extraction process. In a similar fashion, in step **1218**, the frequency domain components of the data passes through a frequency domain correlator and feature extractor. In step **1220**, the outputs from the time domain correlator and feature extraction process of step **1216** and the frequency domain correlator and feature extractor of step **1218** are compared to a reference pattern and feature library, to determine whether the features contained

within the signal of interest match known disease modalities as recorded and maintained within the reference pattern and feature library.

At step **1222**, the outputs from the time domain correlator and feature extraction process of step **1216**, the frequency domain correlator and feature extractor process of step **1218** and the results from the reference pattern and feature library comparison of step **1220** are subjected to a recognition logic decision, where a determination is made as to whether a disease or adverse condition is indicated. At step **1224**, the new disease modality indicated in the recognition logic decision of step **1222** is then used to update the reference pattern and feature library of step **1220**. In step **1226** a desired display mode such as depicted in Figures 10a, 10b and 10c is chosen for subsequent display on the monitor **112**. At step **1228** the process is either terminated at step **1240** or begun anew at step **1202**.

The preceding descriptions of the operation of the present invention are merely illustrative. In various embodiments of the disclosed invention operational steps may be added, eliminated, performed in parallel or performed in a differing order.

METHOD

Sonospectrography can be used as a primary source of auscultatory information in a routine physical examination or in population screening. Sonospectrography can be used in cardiology and general medicine for the detection of functional and organic disorders of the heart such as congenital defects, valve function, diseases of the pericardium and myocardium and systemic and pulmonary hypertension. Sonospectrography can also be used as a traditional stethoscope to capture sounds generated by other organs, such as the lungs, trachea, larynx, liver and carotid arteries.

Elevated blood pressure has a number of causes. Regardless of the cause, however, recent testing at the Uniformed Services University of Health Sciences shows that there is a change in the frequency spectrum of both the aortic and pulmonary semilunar valve sounds that is directly correlated to change in blood pressure of the associated systemic or pulmonary circulatory system. This correlation was shown to be both measurable and repeatable in testing on animals having systemic and pulmonary circulatory systems comparable to the human system.

Elevated blood pressure increases back pressure at associated heart valves. This

increased back pressure results in more rapid closure of the heart valves and a resultant audible "snap" of the valve leaflets. The acoustic signature that is associated with those heart valve sounds has elevated frequency components as compared to the signature associated with heart valves operating under normal blood pressures. As the blood pressure increases, this frequency component also increases. It has been determined that this change in the frequency component is transitory and returns to normal when the blood pressure returns to normal.

Thus, where the sound emitted by the aortic semilunar valve is of an increased frequency, this is indicative of higher systemic blood pressure. Similarly, where the sound emitted by the pulmonary semilunar valve is of an increased frequency, this is indicative of higher pulmonic blood pressure. Through the use of the apparatus of the present invention, it is possible to detect and record sounds originating from the aortic and pulmonary semilunar valves.

In practice, a sensor assembly is placed in contact with the patient. One side of the sensor assembly contains an acoustic coupler that is placed in contact with the patient's skin at the traditional auscultation point for the valve of interest, while a second acoustic coupler on the opposite side faces away from the patient. This second acoustic coupler is designed to acquire background sounds in synchronism with the acoustic coupler in contact with the patient's skin to reject common mode signals reaching both couplers. While breathing normally the sounds of the aortic and/or pulmonary semilunar valves are acquired, preamplified and sent to a plurality of locations.

One analog signal is sent directly to an audio amplifier and high fidelity earphones. A second analog signal is sent through a gain control potentiometer to an analog to digital converter. The data is digitized and displayed in real time on a monitor. Visual feedback from the monitor allows a precise setting of the gain control by the physician for the optimum acquisition of data. In an alternative embodiment, an electronic strip chart is used in the precise setting of the gain control. The physician adjusts gain control to maximize the dynamic range of the captured signal.

In one embodiment, sounds are filtered normally. In an alternative embodiment, sounds are filtered to de-emphasize interfering responses prior to being sent to the earphones or the analog to digital converter. Data can be stored digitally, recalled for future analysis or transmitted to another location.

Referring to Figure 12, data from recent in-vivo testing on animal subjects at the

Uniformed Services University of Health Sciences is shown. The subject had a pressure catheter emplaced to provide actual pressure readings, and the present invention detected, and processed the acoustic signature data from the second heart sounds. Figure 12 plots the relationship between second heart sound A2 **1302**, and blood pressure **1304**. As shown, where there is a rise in the frequency of second heart sound **1302**, there is a corresponding rise in systolic pressure **1306**, mean pressure **1308** and diastolic pressure **1310**.

The subject whose pressure/frequency relationship is depicted in Figure 12, had a resting systolic pressure of about 120 mm Hg, a resting diastolic pressure of about 77 mm Hg, and a predominant second heart sound frequency of 28.5 Hz. The mean blood pressure was thus about 90 mm Hg at 28.5 Hz. As the subject's blood pressure was artificially increased, the associated frequency components of the second heart sound correspondingly increased. Systolic pressure **1306** of the subject reached about 165 mm Hg, diastolic pressure **1310** reached about 85 mm Hg, and frequency of second heart sound **1302** reached 36. Mean pressure **1308** reached about 115 mm Hg. The slope of this mean pressure/frequency curve is approximately 2 mm Hg per Hz. This pressure/frequency correlation was demonstrated in each animal subject tested.

Across a population, measurement of the sound frequency associated with the closure of the aortic and pulmonary semilunar valves will allow an estimate of the mean systemic and pulmonary blood pressure. Specifically, using a range of pressure/frequency curves collected from population samples, the present invention will allow an estimate of the mean systemic and pulmonary pressure with a passive and non-invasive acoustic measurement of the acoustic signature of the semilunar valve closure. As an example, if the mean pressure data curve **1307** in Figure 12 presented an accumulated average from the population, then measurement of a pulmonary semilunar valve closure sound frequency of 36 Hz **1309** would provide an estimate that the mean pulmonic pressure was 115 mm Hg **1311**. In an otherwise asymptomatic patient, this might provide sufficient clinical justification for use of an invasive blood pressure catheter, with the attendant risk and cost, to confirm the pulmonic pressure.

Although the method of the present invention has been described in detail for purpose of illustration, it is understood that such detail is solely for that purpose, and variations can be made therein by those skilled in the art without departing from the spirit and scope of the invention. The apparatus, operation and method of the present invention is defined by the following claims.

WHAT IS CLAIMED IS:

1. An apparatus for monitoring blood pressure comprising:

a means for detecting audio signals;

a means for signal processing connected to the signal detecting means;

a means for signal storage connected to the signal processing means; and

a means for monitoring, connected to the signal processing means.

2. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the audio signal detecting means is a sensor assembly.

3. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the audio signal detecting means is a plurality of sensor assemblies.

4. An apparatus for monitoring blood pressure as claimed in claim 2, wherein the sensor assembly comprises:

a housing having a front and a back;

an electronic module connected to the housing;

a shock dampener connected to the front of the housing;

a means for mounting connected to the housing;

a transducer connected to the mounting means;

an acoustic coupling connected to the transducer; and

a cover connected to the back of the housing.

5. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the housing further comprises a sound deadening material.

6. An apparatus for monitoring blood pressure as claimed in claim 5, wherein the housing further comprises nickel plated aluminum.

7. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the housing further comprises:

a rim having an inside and an outside, located on the periphery of the front of the housing;

a first indentation having an inside and an outside, that runs parallel and adjacent to the inside of the rim;

a second indentation that runs parallel and adjacent to the inside of the first indentation;

and

a bore that is approximately centrally located within the second indentation.

8. An apparatus for monitoring blood pressure as claimed in claim 7, wherein the electronic module nests within the bore.

9. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the shock dampener is an "O" ring.

10. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the mounting means is a plastic mounting ring.

11. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the transducer is a piezoelement.

12. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the acoustic coupling is a parametric acoustic transconductor.

13. An apparatus for monitoring blood pressure as claimed in claim 12, wherein the parametric acoustic transconductor comprises latex foam.

14. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the signal processing means is a computer with a central processing unit.

15. An apparatus for monitoring blood pressure as claimed in claim 14, wherein the computer with a central processing unit is an IBM compatible personal computer.

16. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for signal storage further comprises an array of disks.

17. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for signal storage further comprises an internal hard disk drive.

18. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for signal storage further comprises an internal hard disk drive.

19. An apparatus for monitoring blood pressure as claimed in claim 1, further comprising:

a means for hard copy reproduction connected to the signal processing means.

20. An apparatus for monitoring blood pressure as claimed in claim 19, wherein the means for hard copy reproduction further comprises a printer.

21. An apparatus for monitoring blood pressure as claimed in claim 1, further comprising:

a means for remote connection connected to the signal processing means.

22. An apparatus for monitoring blood pressure as claimed in claim 21, wherein the means for remote connection further comprises a modem.

23. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for monitoring further comprises a high resolution EGA color display monitor.

24. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the means for monitoring further comprises a high resolution VGA color display monitor.

25. An apparatus for monitoring blood pressure as claimed in claim 1, further comprising:

a means for data acquisition connected to the signal detection means and the signal processing means.

26. An apparatus for monitoring blood pressure as claimed in claim 25, wherein the means for data acquisition comprises an amplifier.

27. An apparatus for monitoring blood pressure as claimed in claim 26, wherein the amplifier comprises a tailored bandpass amplifier.

28. An apparatus for monitoring blood pressure as claimed in claim 27, wherein the tailored bandpass amplifier comprises a low frequency response from a predetermined first point to a predetermined second point, and a higher frequency response of a predetermined level, from the predetermined second point to a predetermined third point.

29. An apparatus for monitoring blood pressure as claimed in claim 28, wherein the predetermined level is about 20 dB.

30. An apparatus for monitoring blood pressure as claimed in claim 28, wherein the predetermined first point is about 100 Hz, the predetermined second point is about 100 Hz and the predetermined third point is about 600 Hz.

31. An apparatus for monitoring blood pressure as claimed in claim 28, where in the predetermined second point is about 60 Hz.

32. A method of determining blood pressure comprising:

performing initialization procedures;

acquiring physiologic signals;

acquiring background signals;

subtracting background signals from physiologic signals creating physiologic data;

processing physiologic data forming a time domain output and a frequency domain data output;

comparing the time domain output and the frequency domain output with a reference pattern and feature library; and

determining if a disease modality is indicated.

33. A method of determining blood pressure as claimed in claim 32, wherein performing initialization further comprises:

initializing system;

calibrating system;

selecting sensors;

inputting patient parameters; and

clearing buffers.

34. A method of determining blood pressure as claimed in claim 32, wherein acquiring physiologic signals comprises acquiring acoustic signals.

35. A method of determining blood pressure as claimed in claim 32, wherein acquiring physiologic signals comprises acquiring electric signals.

36. A method of determining blood pressure as claimed in claim 32, wherein the physiologic signals are in an analog form, further comprising:

converting, the physiologic signals from the analog form to a digital form.

37. A method of determining blood pressure as claimed in claim 32, wherein the background signals are in an analog form, further comprising the step:

converting the background signals from the analog form to a digital form.

38. A method of determining blood pressure as claimed in claim 32, wherein processing further comprises:

applying signal conditioning and time domain averaging to the physiologic data forming conditioned and averaged data;

formatting the conditioned and averaged data in an array creating formatted data;

aligning and normalizing formatted data, creating aligned and formalized data;

normalizing and integrating the aligned and formalized data, creating normalized and integrated data, wherein said normalized and integrated data has time domain components and frequency domain components;

passing the time domain components of the normalized and integrated data through a time domain correlator and feature extraction process; and

passing the frequency domain components of the normalized and integrated data through a frequency domain correlator and feature extractor, creating the time domain output and the frequency domain output.

39. A method of determining blood pressure as claimed in claim 38, further comprising:

displaying the formatted data on a monitor.

40. A method of determining blood pressure as claimed in claim 38, further comprising:

displaying the aligned and normalized data on a monitor.

41. A method of determining blood pressure as claimed in claim 38, further comprising:

displaying the normalized and integrated data on a monitor.

42. A method of determining blood pressure as claimed in claim 32, further comprising:

updating the reference pattern and feature library.

43. A method of determining systemic blood pressure using sonospectrography analysis comprising:

monitoring the frequency of a sound emitted by the aortic semilunar valve, wherein the sound is detected using a sensor assembly, to monitor physiologic signals, the sensor assembly comprising:

a housing having a front and a back;

an electronic module connected to the housing;

a shock dampener connected to the front of the housing;

a means for mounting connected to the housing;

an acoustic coupler connected to the mounting means;

a transducer connected to the acoustic coupler; and

a cover connected to the back of the housing;

processing the physiologic signals, the processing comprising:

applying signal conditioning and time domain averaging to the physiologic signals

to form conditioned and averaged data;

formatting the conditioned and averaged data in an array to create formatted data;

aligning and normalizing formatted data, to create aligned and formalized data;

normalizing and integrating the aligned and formalized data, to create normalized and integrated data that has time domain components and frequency domain components;

passing the time domain components of the normalized and integrated data through a time domain correlator and feature extraction process;

passing the frequency domain components of the normalized and integrated data through a frequency domain correlator and feature extractor, to create a time domain output and a frequency domain output;

comparing time domain output and the frequency domain output with a reference pattern and feature library; and

determining if a disease modality is indicated.

44. A method of determining systemic blood pressure using sonospectrography analysis as claimed in claim 43, further comprising:

acquiring background signals; and

subtracting background signals from physiologic signals.

45. A sensor assembly for detecting physiological sounds comprising:

a housing having a front and a back;

an electronic module connected to the housing;

a shock dampener connected to the front of the housing;

a means for mounting connected to the shock dampener;

an acoustic coupler connected to the mounting means;

a transducer connected to the acoustic coupler; and

a cover connected to the back of the housing.

46. A sensor assembly as claimed in claim 45, wherein the housing further comprises a sound deadening material.

47. A sensor assembly as claimed in claim 46, wherein the housing further comprises nickel plated aluminum.

48. A sensor assembly as claimed in claim 45, wherein the housing further comprises:

a rim having an inside and an outside, that is located on the periphery of the front of the housing;

a first indentation having an inside and an outside, that runs parallel and adjacent to the inside of the rim;

a second indentation that runs parallel and adjacent to the inside of the first indentation; and

a bore, that is approximately centrally located within the second indentation.

49. A sensor assembly as claimed in claim 48, wherein the electronic module nests within the bore.

50. A sensor assembly as claimed in claim 45, wherein the shock dampener is an "O" ring.

51. A sensor assembly as claimed in claim 45, wherein the mounting means is a plastic mounting ring.

52. A sensor assembly as claimed in claim 45, wherein the transducer is a piezoelement.

53. A sensor assembly as claimed in claim 52, wherein the acoustic coupling is a parametric acoustic transconductor.

54. A sensor assembly as claimed in claim 53, wherein the parametric acoustic transconductor comprises latex foam.

55. A sensor assembly for detecting physiological sounds comprising:

a housing, having a front, a back, and an interior;

an electronic module that nests in the interior of the housing;

a first shock dampener connected to the front of the housing;

a first mounting means connected to the first shock dampener;

a transducer connected to the first mounting means;

a first acoustic coupling connected to the transducer;

a second shock dampener connected to the back of the housing;

a second mounting means connected to the second shock dampener;

a second transducer connected to the second mounting means; and

a second acoustic coupling connected to the second transducer.

56. A sensor assembly as claimed in claim 55, wherein the housing further comprises

a sound deadening material.

57. A sensor assembly as claimed in claim 56, wherein the housing further comprises nickel plated aluminum.

58. A sensor assembly as claimed in claim 55, wherein the housing further comprises:

a first rim having an inside and an outside, that is located on the periphery of the front of the housing;

a first indentation having an inside and an outside, that runs parallel and adjacent to the inside of the first rim;

a second indentation that runs parallel and adjacent to the inside of the first indentation;

a bore, that is approximately centrally located within the second indentation;

a second rim having an inside and an outside, that is located on the periphery of the back of the housing;

a third indentation having an inside and an outside, that runs parallel and adjacent to the inside of the second rim; and

a fourth indentation, that runs parallel and adjacent to the inside of the third indentation.

59. A sensor assembly as claimed in claim 58, wherein the electronic module nests within the bore.

60. A sensor assembly as claimed in claim 58, wherein the first shock dampener is an "O" ring and the second shock dampener is an "O" ring.

61. A sensor assembly as claimed in claim 58, wherein the first mounting means is a plastic mounting ring and the second mounting means is a plastic mounting ring.

62. A sensor assembly as claimed in claim 58, wherein the first transducer is a piezoelement and the second transducer is a piezoelement.

63. A sensor assembly as claimed in claim 58, wherein the first acoustic coupling is a parametric acoustic transconductor and the second acoustic coupling is a parametric acoustic transconductor.

64. A sensor assembly as claimed in claim 58, wherein the parametric acoustic transconductor comprises latex foam.

65. An apparatus for determining blood pressure comprising:

an acoustic coupling, wherein the acoustic coupling provides a low-loss acoustic transmission coupling between skin and a piezoelectric transducer.

66. An apparatus for determining blood pressure as claimed in claim 65, wherein the acoustic coupling is a parametric acoustic transconductor.

67. An apparatus for determining blood pressure as claimed in claim 65, wherein the acoustic coupling has a high conduction coefficient.

68. An apparatus for determining blood pressure as claimed in claim 65 wherein the acoustic coupling comprises latex foam.

69. An apparatus for monitoring blood pressure comprising:

an acoustic coupling;

a transducer connected to the acoustic coupling;

an electronic module connected to the transducer;

a data acquisition module connected to the electronic module; and

a data cable connected to the electronic module and the data acquisition module.

70. An apparatus for monitoring blood pressure as claimed in claim 69, wherein the data cable is a twisted shielded pair.

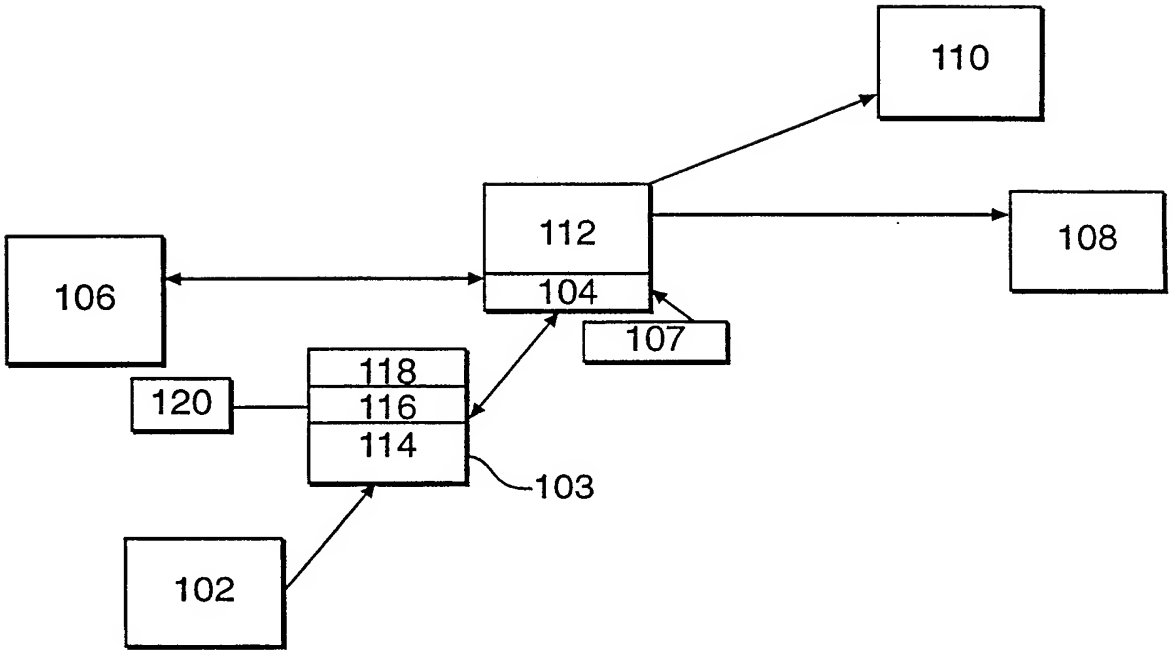

FIG. 1

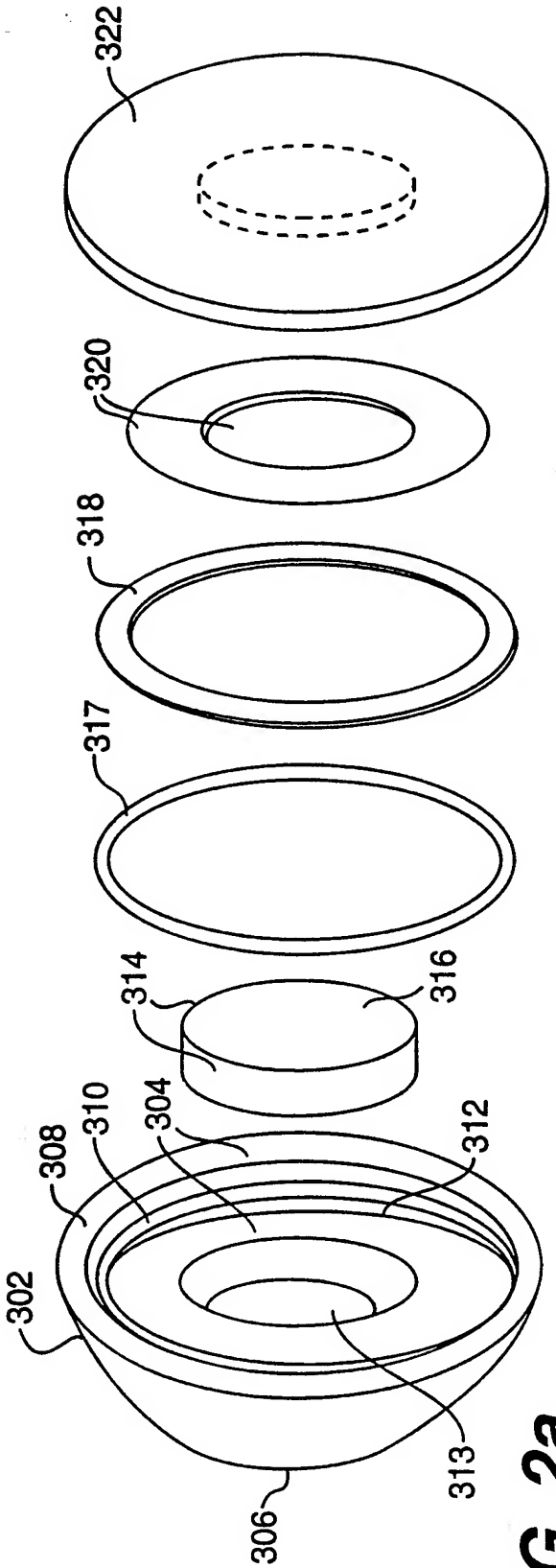
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FIG. 2a

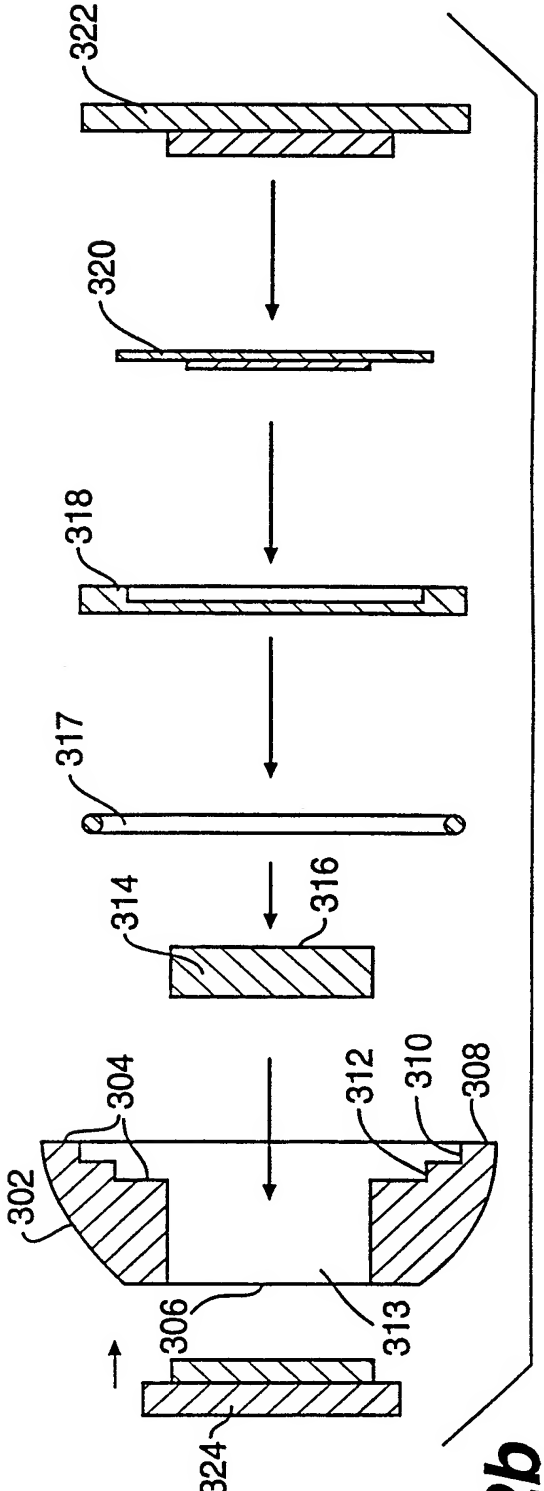
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FIG. 2b

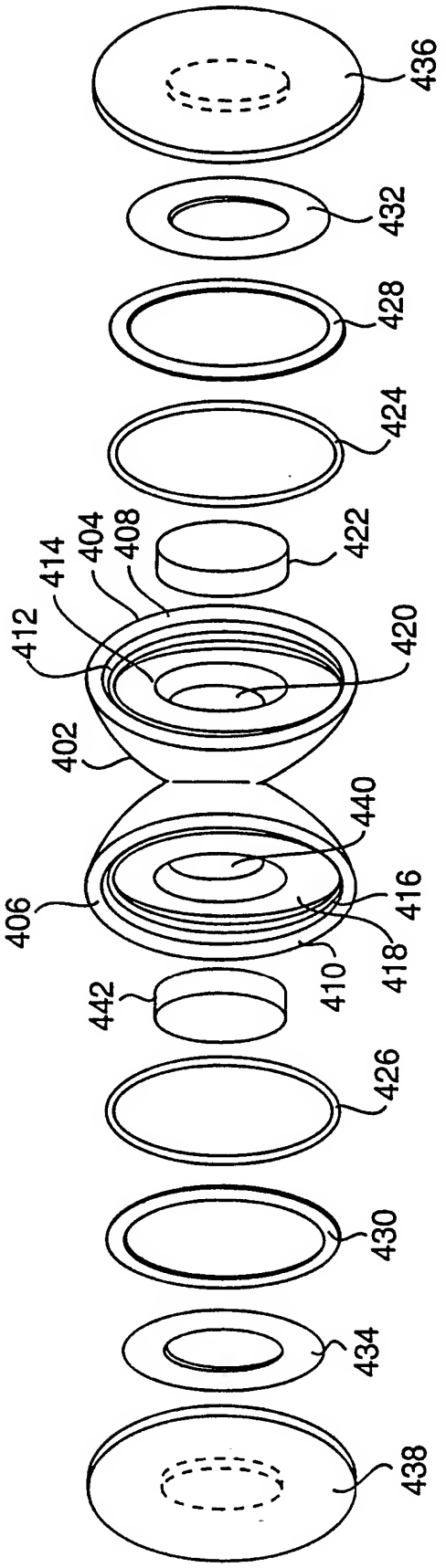
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FIG. 3

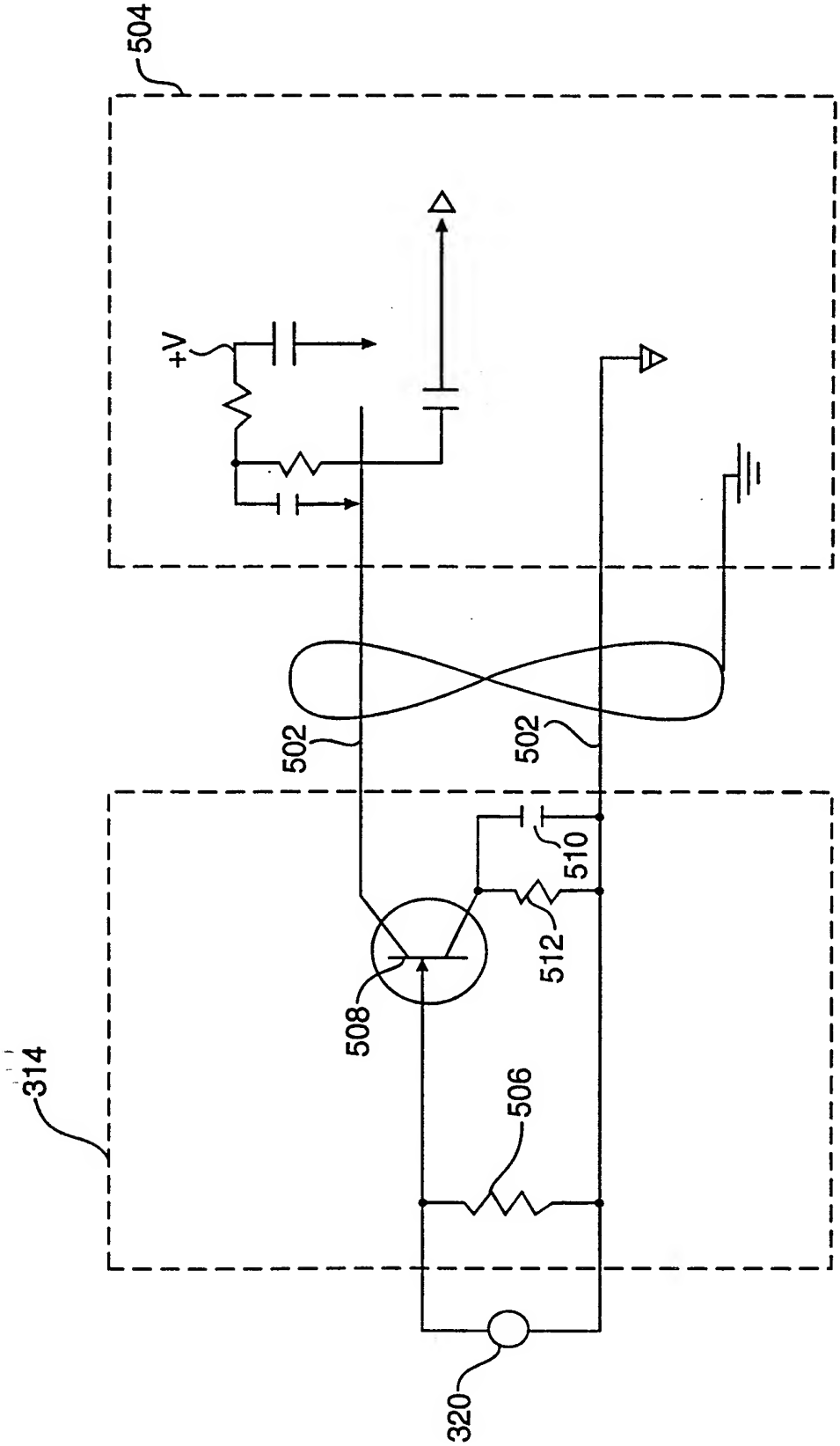


FIG. 4

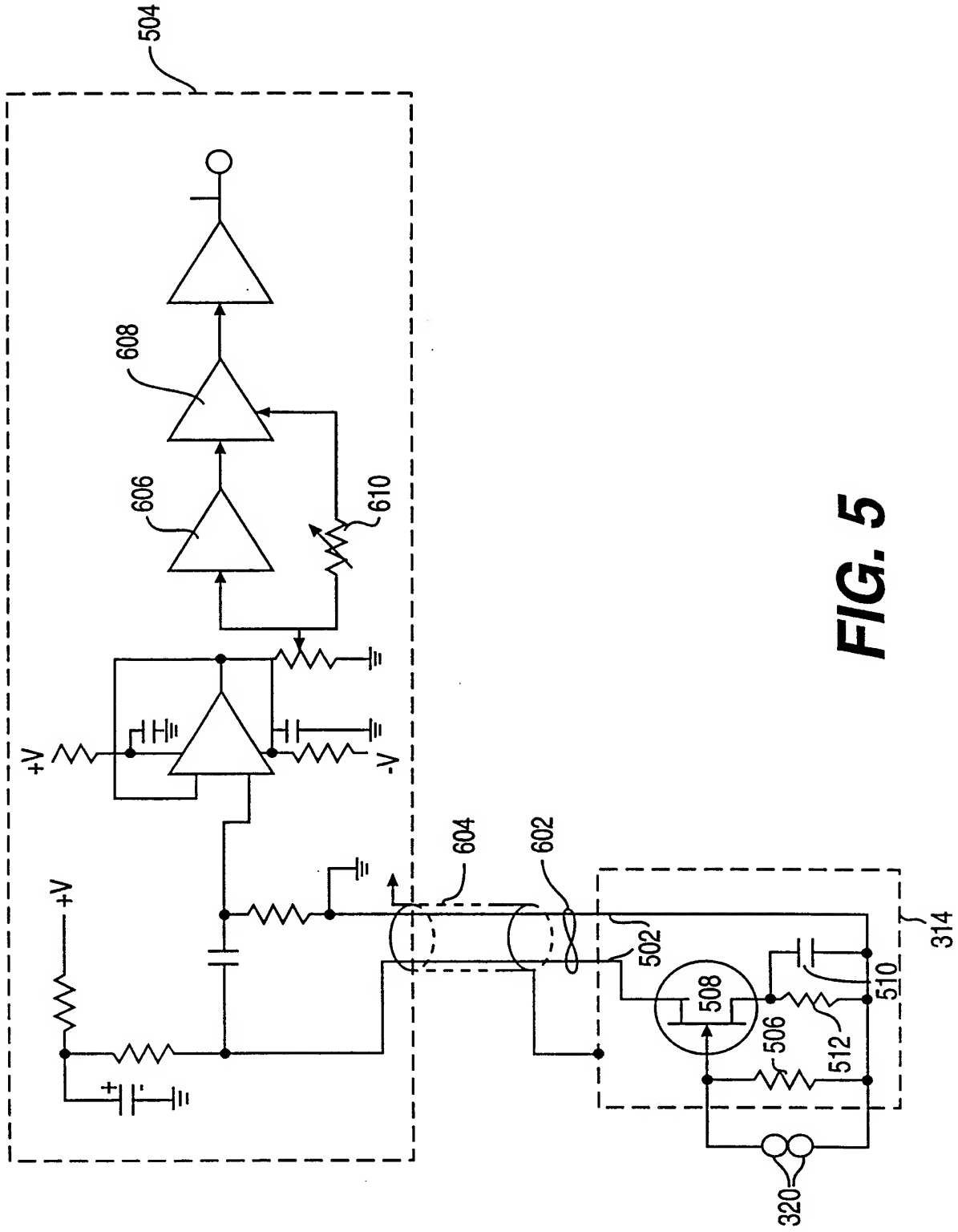


FIG. 5

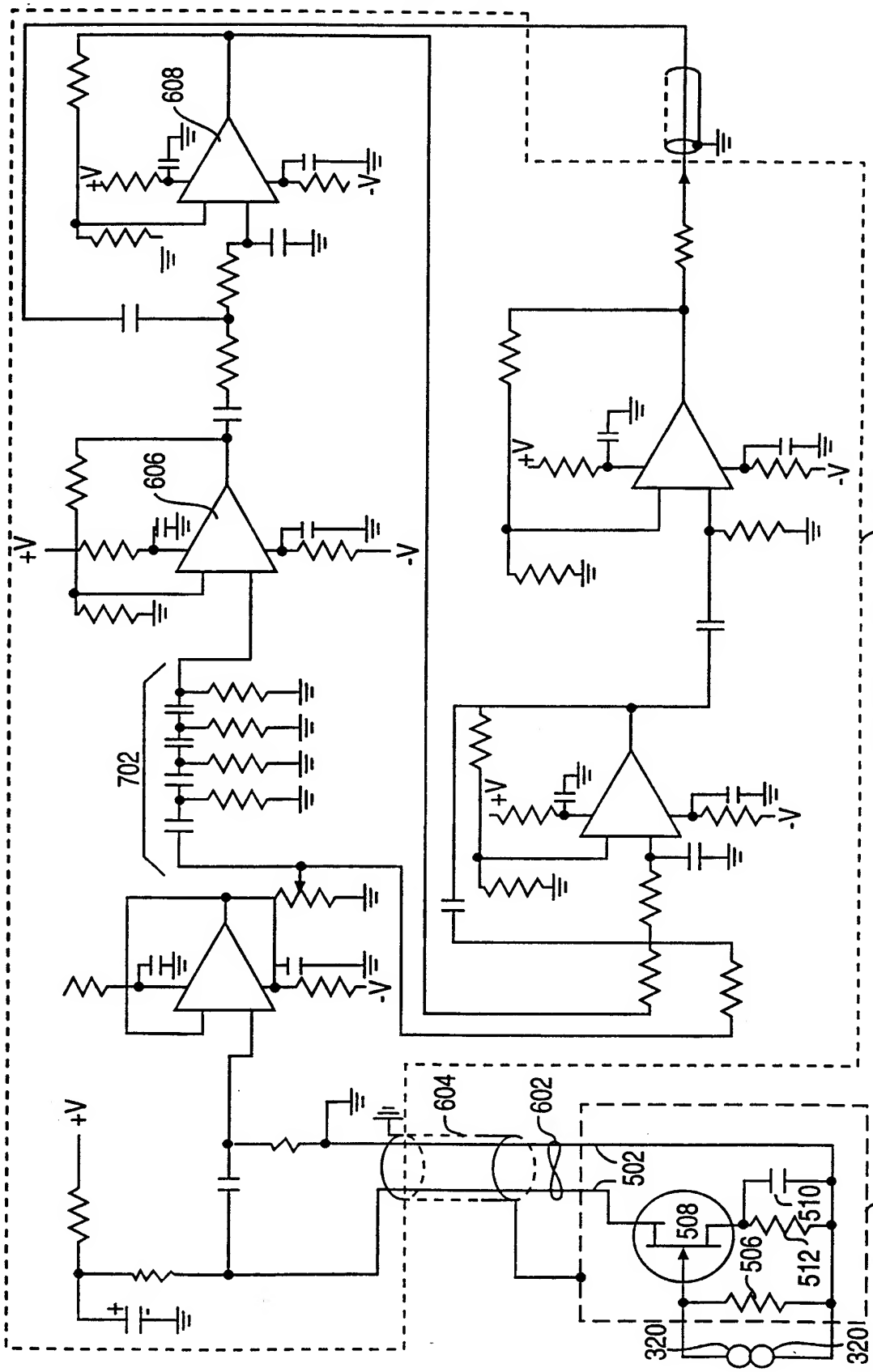


FIG. 6

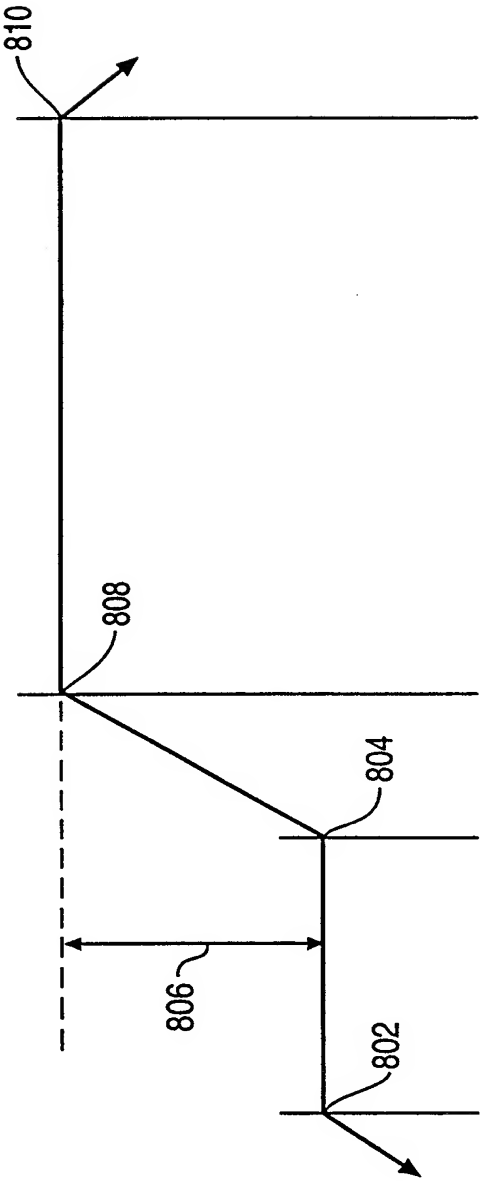


FIG. 7

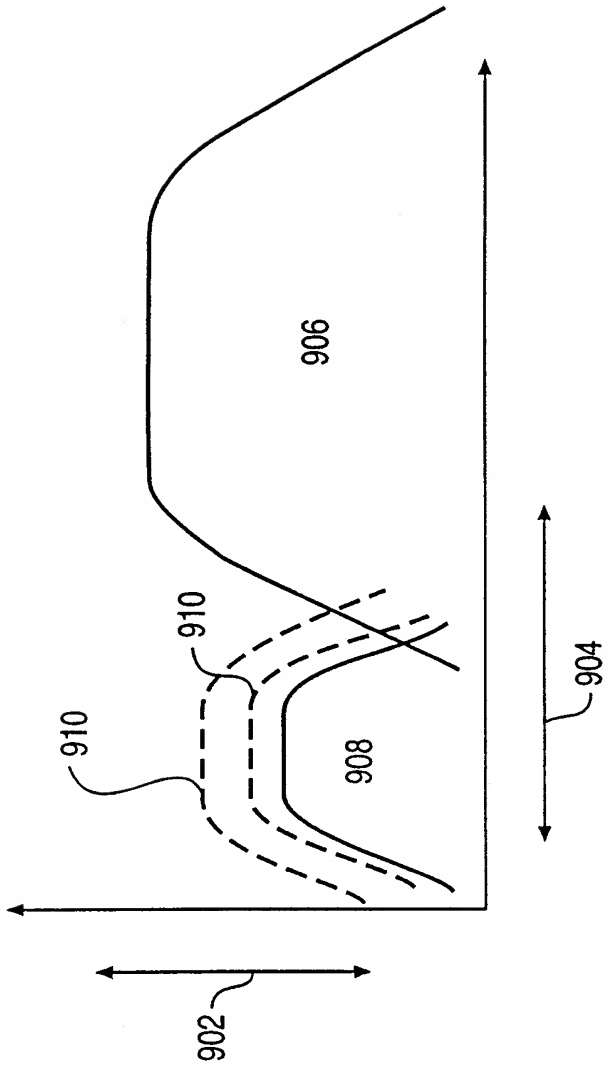
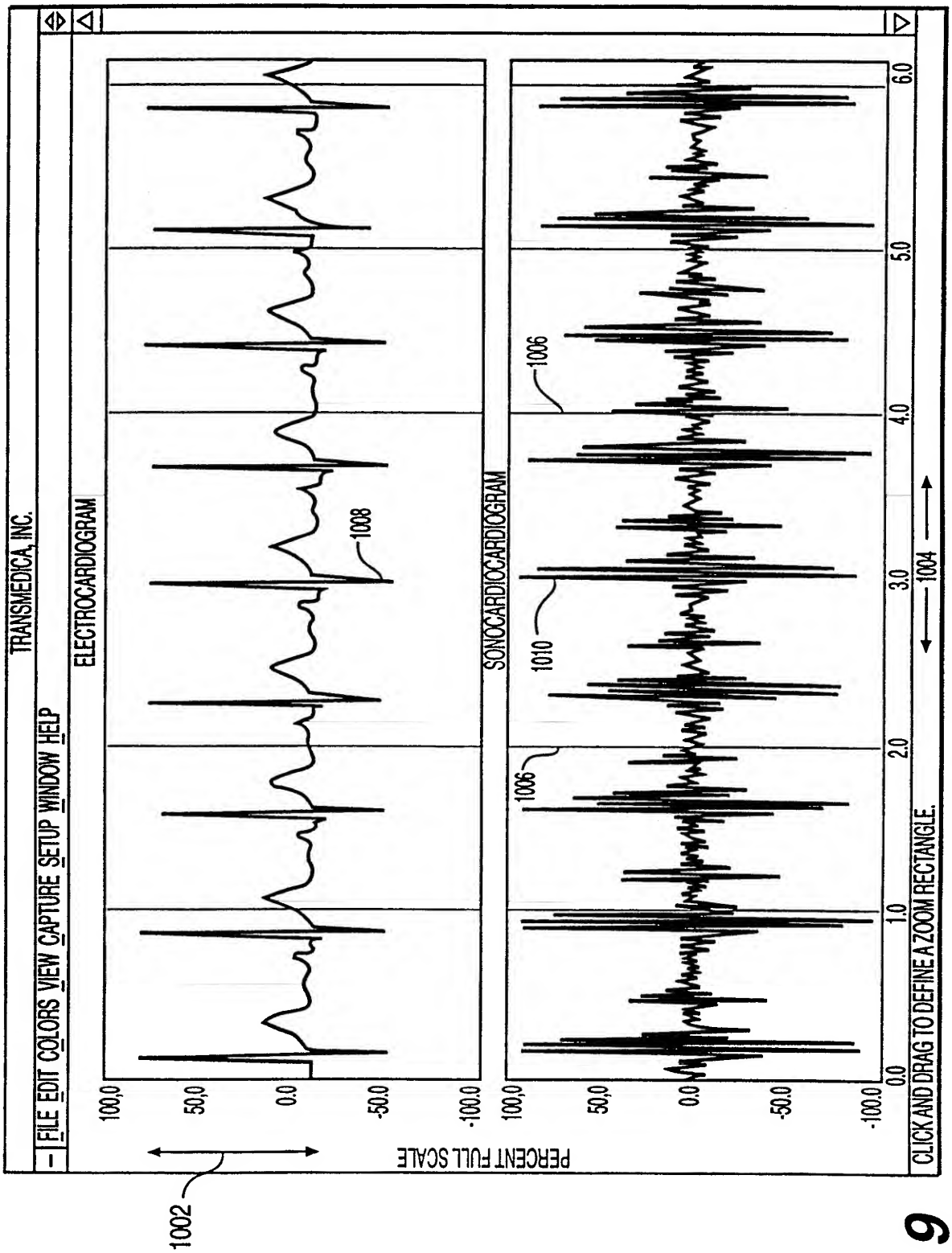


FIG. 8


TRANSMEDICA, INC.
FILE EDIT COLORS VIEW CAPTURE SETUP WINDOW HELP
ELECTROCARDIOGRAM
SONOCARDIOGRAM
1002
1004
1006
1008
1010
PERCENT FULL SCALE
100,0
50,0
0.0
-50.0
-100.0
0.0
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2.0
3.0
4.0
5.0
6.0
CLICK AND DRAG TO DEFINE A ZOOM RECTANGLE.

FIG. 9

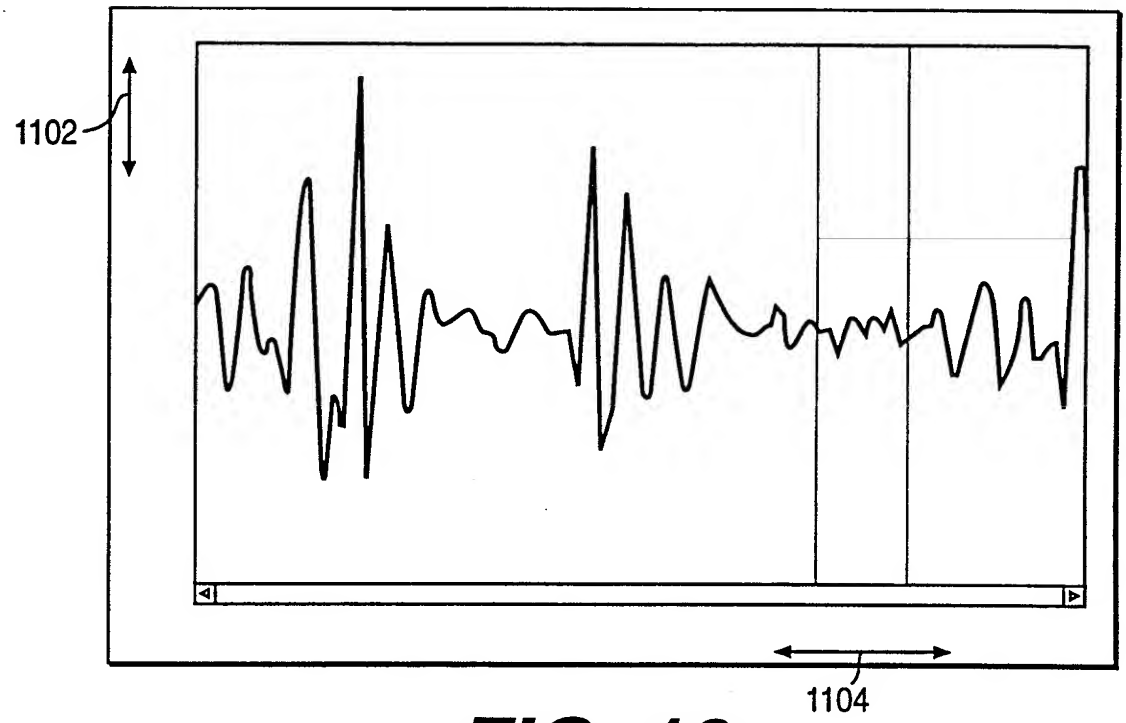


FIG. 10a

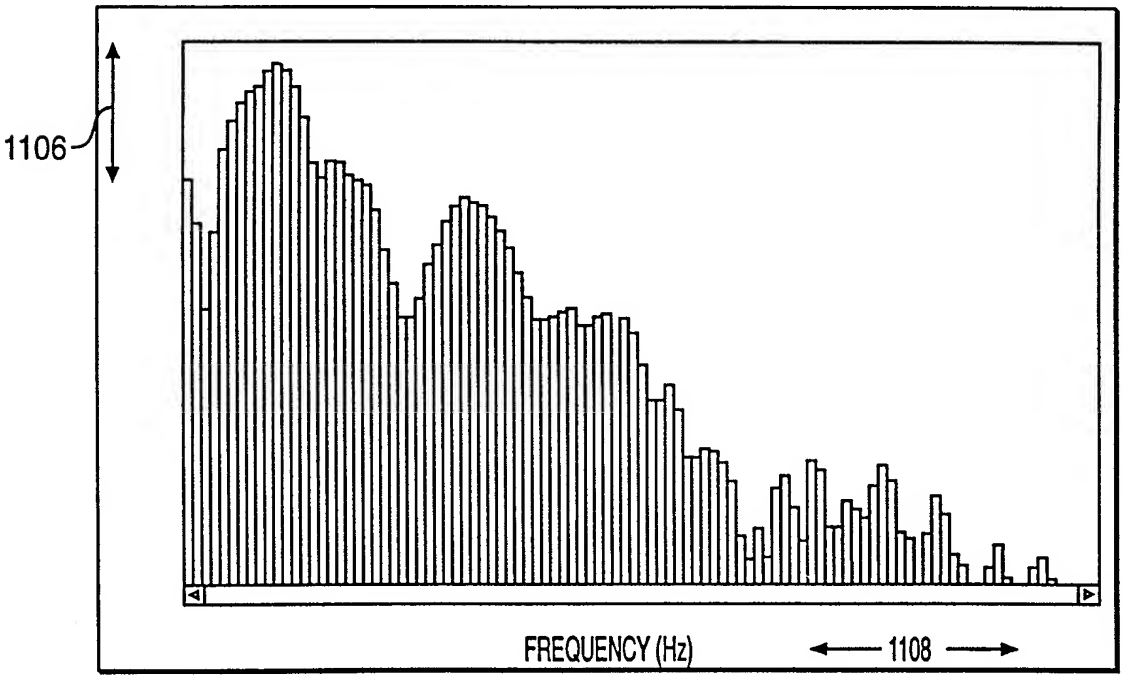
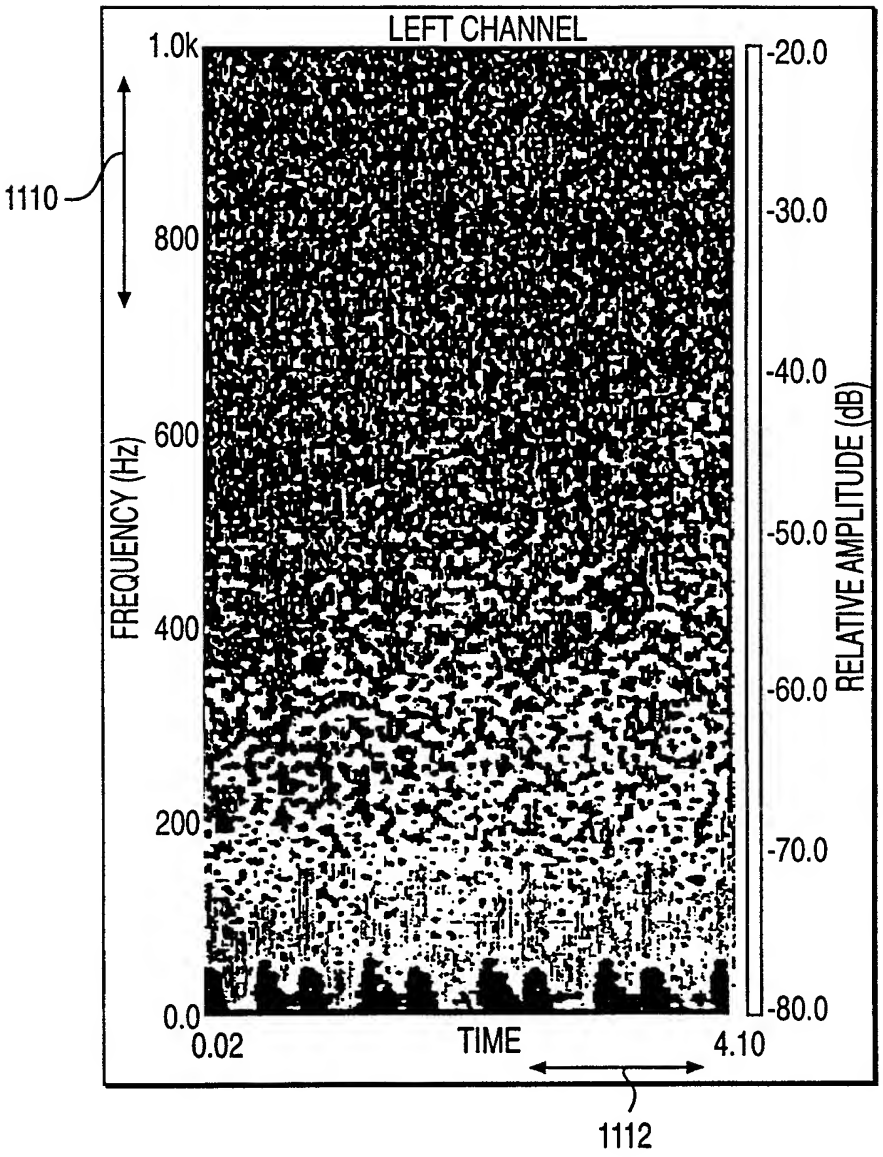


FIG. 10b


LEFT CHANNEL
1.0k
800
600
400
200
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FREQUENCY (Hz)
1110
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TIME
4.10
1112
-20.0
-30.0
-40.0
-50.0
-60.0
-70.0
-80.0
RELATIVE AMPLITUDE (dB)

FIG. 10c

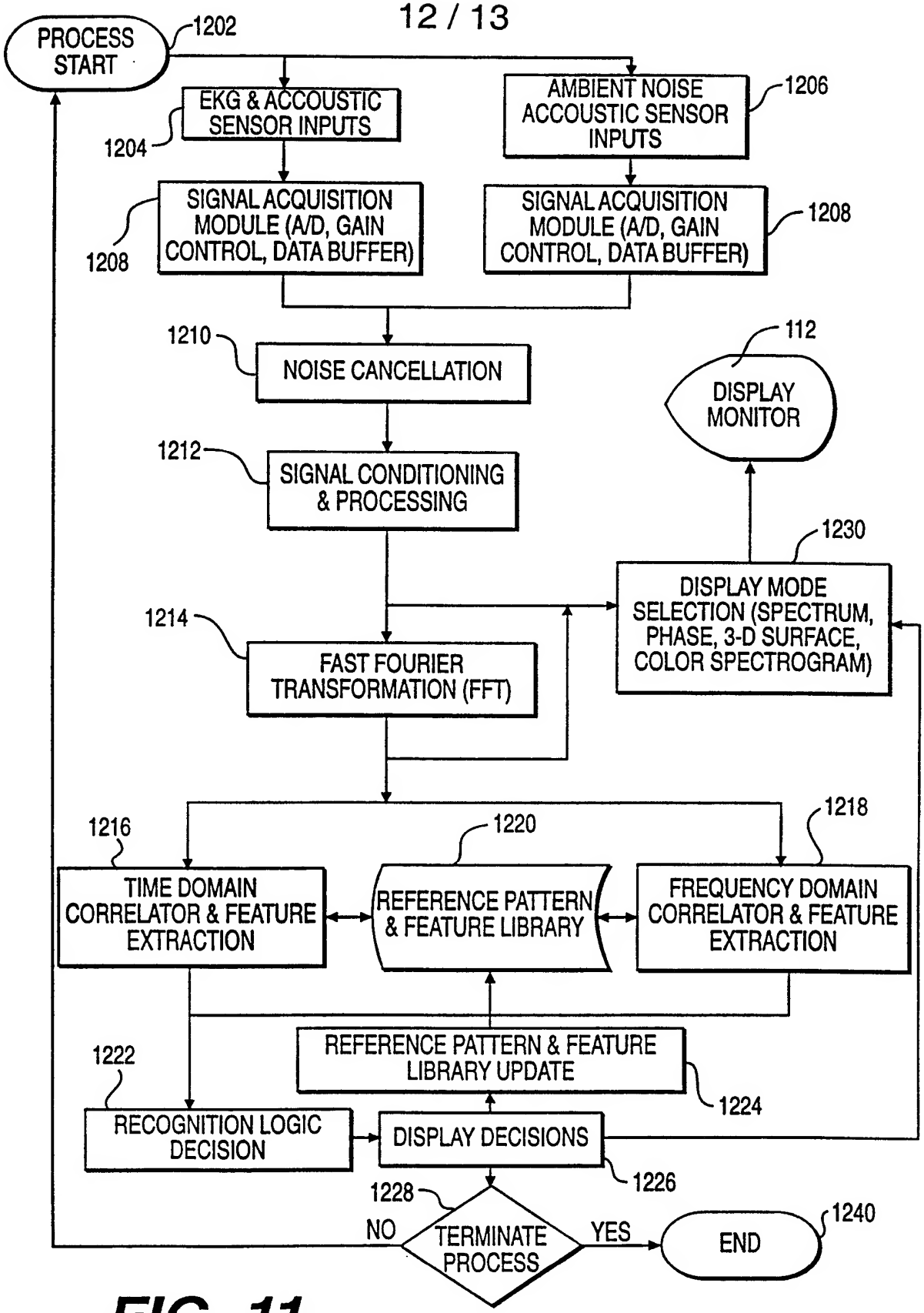
PROCESS START
1202
EKG & ACCOUSTIC SENSOR INPUTS
1204
AMBIENT NOISE ACCOUSTIC SENSOR INPUTS
1206
SIGNAL ACQUISITION MODULE (A/D, GAIN CONTROL, DATA BUFFER)
1208
SIGNAL ACQUISITION MODULE (A/D, GAIN CONTROL, DATA BUFFER)
1208
NOISE CANCELLATION
1210
DISPLAY MONITOR
112
SIGNAL CONDITIONING & PROCESSING
1212
DISPLAY MODE SELECTION (SPECTRUM, PHASE, 3-D SURFACE, COLOR SPECTROGRAM)
1230
FAST FOURIER TRANSFORMATION (FFT)
1214
TIME DOMAIN CORRELATOR & FEATURE EXTRACTION
1216
REFERENCE PATTERN & FEATURE LIBRARY
1220
FREQUENCY DOMAIN CORRELATOR & FEATURE EXTRACTION
1218
REFERENCE PATTERN & FEATURE LIBRARY UPDATE
1224
RECOGNITION LOGIC DECISION
1222
DISPLAY DECISIONS
1226
TERMINATE PROCESS
1228
NO
YES
END
1240

FIG. 11

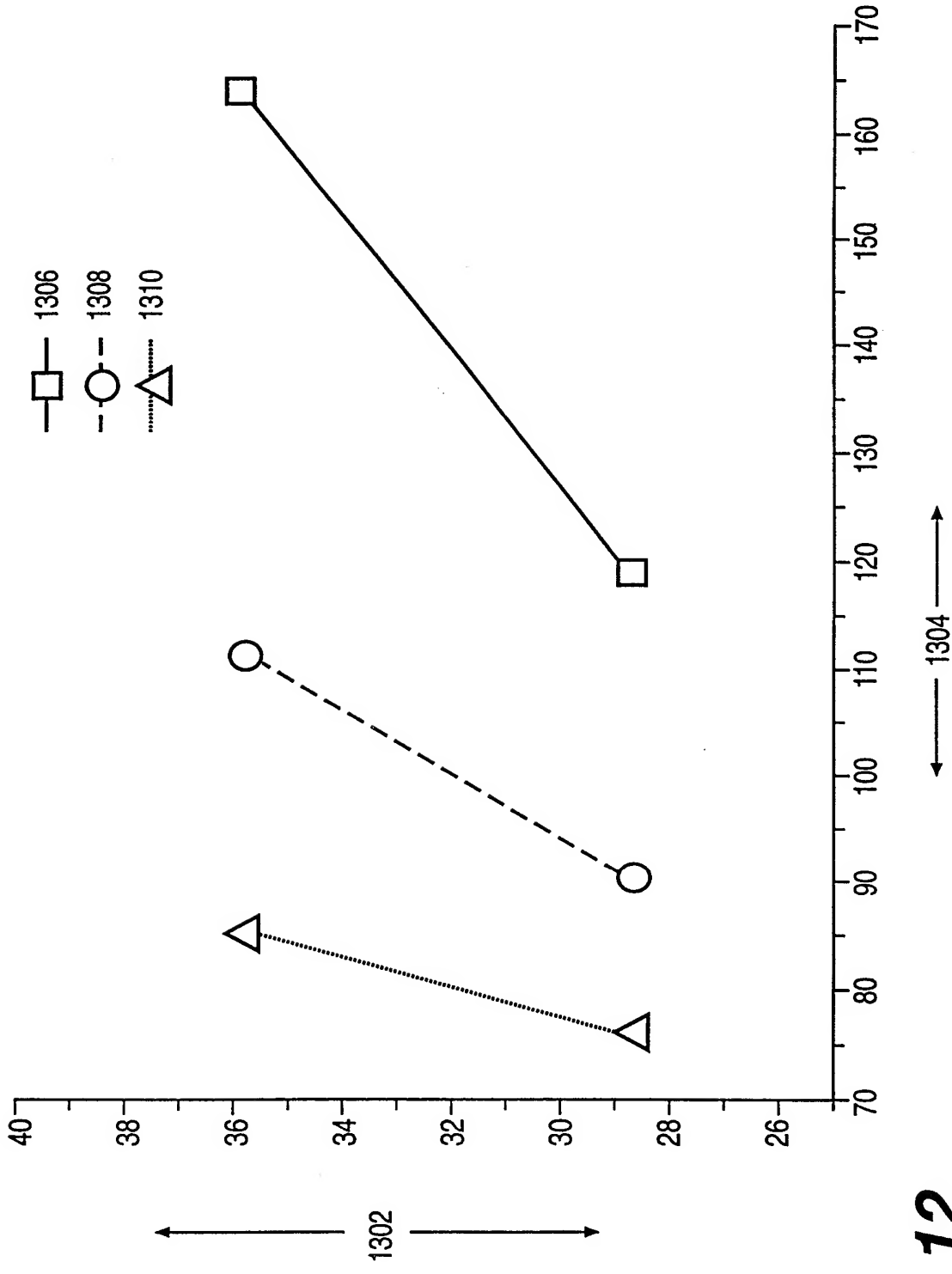
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FIG. 12

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 97/21917

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B7/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 020 110 A (W.J. KASPARI) 10 December 1980	1-4,7, 9-11,14, 25,26, 32, 34-37, 39, 43-45, 48, 50-52, 60-62, 65,69
A	see page 3, line 4 - line 37	6,47,55
A	see page 7, line 11 - page 9, line 18 see page 12, line 24 - page 17, line 17	57,58

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
7 April 1998	17/04/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rieb, K.D.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 97/21917

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 467 775 A (T.F. CALLAHAN ET AL.) 21 November 1995	1-3,5, 10,14, 21, 25-28, 44-46, 48,51, 55,56,69
A	see column 4, line 41 - column 5, line 17	32-37
A	see column 6, line 5 - column 7, line 28	43,58
A	see column 8, line 5 - line 44 see column 11, line 56 - column 12, line 55	65,67

A	US 4 967 760 A (W.R. BENNETT, JR. ET AL.) 6 November 1990 cited in the application	1-5,14, 19,20
A	see column 1, line 25 - line 53	25-28
A	see column 4, line 1 - line 63	32-36,39
A	see column 9, line 9 - column 10, line 45	40,43-46
A	see column 10, line 66 - column 11, line 24 see column 13, line 64 - column 15, line 31	55,56, 65,67,69

A	US 5 025 809 A (K.H. JOHNSON ET AL.) 25 June 1991	1,14,25, 32,34-36
A	see column 6, line 19 - column 9, line 20	38-43

A	US 5 205 295 A (B. DEL MAR ET AL.) 27 April 1993	1,14, 16-20, 25,35
A	see column 9, line 46 - column 11, line 44	36,38-42

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/US 97/21917

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		AT 9056 T	15-09-84
		CA 1161274 A	31-01-84
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US 5467775 A	21-11-95	AU 5313196 A	08-10-96
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		WO 9008503 A	09-08-90
		US 5012815 A	07-05-91
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US 5205295 A	27-04-93	WO 9404075 A	03-03-94